IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD., Plaintiff, v. SAREPTA THERAPEUTICS, INC., Defendant.	C.A. No. 21-1015 (GBW) [redacted]
SAREPTA THERAPEUTICS, INC. and THE UNIVERSITY OF WESTERN AUSTRALIA, Defendant/Counter-Plaintiffs, v. NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC. Plaintiff/Counter-Defendants.	REDACTED - PUBLIC VERSION

SAREPTA THERAPEUTICS, INC'S ADDITIONAL MATERIALS FOR APPENDIX REGARDING NIPPON SHINYAKU CO. LTD AND NS PHARMA, INC.'S OBJECTIONS TO SPECIAL MASTER ORDERS

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APPENDIX
303-304

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU, LTD., Plaintiff, v. SAREPTA THERAPEUTICS, INC., Defendant.	C.A. No. 21-1015-GBW [redacted]
SAREPTA THERAPEUTICS, INC. and UNIVERSITY OF WESTERN AUSTRALIA, Defendant/Counter-Plaintiff, v. NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC., Plaintiff/Counter-Defendants.	

SPECIAL MASTER ORDER #3

Pursuant to Memorandum Opinion and Special Master Order #2 and the Special Master's ruling on Nippon Shinyaku's[1] motion to compel (D.I. 254), on July 10, 2023, Sarepta[2] submitted copies of both the fully unredacted and fully redacted versions of the Roche Agreement for *in camera* review by the Special Master to assess the scope and appropriateness of the redactions.

Having carefully reviewed both documents, the Special Master finds that, with the exception of the redaction to Section 1.72 of the Roche Agreement, all of the other redactions in

[1] Nippon Shinyaku, Ltd. and NS Pharma, Inc. (collectively, "Nippon Shinyaku")
[2] Sarepta Therapeutics, Inc. ("Sarepta")

the fully redacted version of the Roche Agreement are appropriate and properly encompass information that is not relevant to this case, and therefore should remain redacted.

Regarding Section 1.72 of the Roche Agreement, the Special Master finds that the redaction to this section is overbroad because it encompasses at least some information that appears to be relevant to this case, namely, it references the accused Vyondys53® product.

Accordingly, **IT IS HEREBY ORDERED** that, within three (3) business days of this Order, Sarepta shall prepare a revised fully redacted version of the Roche Agreement for production to Nippon Shinyaku that reflects the following revised redaction to Section 1.72 of the Roche Agreement:

> **1.72** "**Exon-Skipping Products**" means any and all products, in any dosage strength, concentration, or formulation, [redacted] that contain antisense oligonucleotides that target the dystrophin gene to induce exon skipping, [redacted] including [redacted] VYONDYS 53® (golodirsen) [redacted]

* * *

This Order is preliminarily submitted under seal as a precaution because the fully unredacted Roche Agreement is identified as highly confidential. Within three (3) business days of this Order, the parties shall jointly email the Special Master and advise of any proposed redactions.

IT IS SO ORDERED.

Dated: July 14, 2023

Monte T. Squire

Special Master Monté T. Squire

APPENDIX
305-325

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU, LTD.,
Plaintiff,
v. C.A. No.
SAREPTA THERAPEUTICS, INC., et al., 21-1015-GBW
Defendants.

CONFIDENTIAL HEARING

DATE: Wednesday, June 21, 2023
TIME: 4:00 p.m.
BEFORE: Special Master Monte T. Squire
LOCATION: Remote Proceeding
Duane Morris LLP
1201 North Market Street, Suite 501
Wilmington, DE 19801
REPORTED BY: Andrew Weader, Notary Public
JOB NO.: 5973942

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I N D E X

WITNESS(ES):	DX	CX	RDX	RCX

E X H I B I T S

NO.	DESCRIPTION	ID/EVD

(None marked.)

your argument.

MS. VENEGAS: Good afternoon, Special Master. Krista Venegas on behalf of Nippon Shinyaku. And so as you saw in our papers, Nippon Shinyaku is moving for Sarepta to produce relevant license agreements in this matter.

And specifically, what we mean by that are an unredacted copy of a license -- publicly available license agreement with Roche that relates to the technology in this case. And I think there's no dispute that that license relates to the technology here.

The dispute as to that license is whether or not we may have a completely unredacted version of that license, which is indisputably relevant.

And then the second part of the issue is whether or not Sarepta will be compelled to produce other license agreements that relate to genetic medicine or the treatment of DMD -- or Duchenne Muscular Dystrophy, which is the disease state that is at issue in this patent litigation.

And I think the parties do agree on the legal framework or reason why these licenses are

generally relevant is, they are relevant to damages in this patent infringement matter, specifically reasonable royalties determined under Georgia-specific factors, two of which relate to a party's either in-licensing, or out-licensing a related technology.

And so both parties, I think, agree on the legal framework that applies to what information is relevant to royalties. And that information includes a party's own licenses.

What Sarepta seems to dispute is whether or not the other licenses that it has not yet produced are sufficiently related to the technology at issue in this case.

And Nippon Shinyaku's position is that those agreements, in fact, are related, because they relate to genetic medicine -- treatment for Duchenne Muscular Dystrophy. And to our knowledge, there are a handful of other license agreements that Sarepta has entered into for other treatments of Duchenne Muscular Dystrophy.

And so we are not asking for all of Sarepta's licenses that it has, or all of its therapeutic categories, but have limited our request to licenses just in the DMD space.

In fact, the question of relevance -- our position is it's not up to Sarepta to decide whether or not those licenses are sufficiently related to the technology at issue in the case.

Rather, that is the -- the comparability of those licenses is an issue for expert inquiry, both from a technical point of view and from an economic point of view. Excuse me. And it should not be left up to Sarepta to internally decide the relevance of those licenses and refuse to produce those licenses on a relevant basis.

The reality is that all of those licenses relate to the treatment of DMD, or Duchenne Muscular Dystrophy.

And there's no dispute that licenses, such as for gene therapy, which are not exon-skipping therapy but a different type of genetic medicine, would also treat DMD patients who have the same genetic disorder that is involved in this case, or exon 53.

So Sarepta cannot dispute that these other technologies are aimed at the same patient populations as are at issue in this case, and therefore are relevant technology for the purpose of

determining royalty, as well as the relevant market for these types of products. All of this will be of interest to our experts.

SPECIAL MASTER: Counsel, could I jump in? I have a quick question. Is it -- I read the papers -- are all the asserted patents, I guess, in both sets of asserted patents -- are they all limited to exon-skipping treatments for DMD, or therapies for DMD?

MS. VENEGAS: That is correct.

SPECIAL MASTER: And the accused products are also -- or the specifically accused products are also all limited to this exon skipping -- specific to exon-skipping DMD therapies; is that correct, too?

MS. VENEGAS: That is correct.

SPECIAL MASTER: And so I just want to understand -- just make sure it's clear. So the justification for other therapies that are non -- I guess, non-exon-skipping therapies -- is it all -- is it all just related to this reasonable royalty? So to this damages, issue, I guess, related to comparable licenses?

MS. VENEGAS: It is related to both

comparable licenses for the purpose of our understanding a reasonable royalty in this case, as well as to understand the relevant markets.

So the patients who are amenable to these treatments are Duchenne Muscular Dystrophy patients and all of these therapies -- genetic medicine therapies are available therapies for the treatment of these patients.

SPECIAL MASTER: And one other set of questions related to that. Putting the Roche Agreement aside, is it correct that you're looking for all license agreements related to DMD therapies, and all agreements related to these antisense oligonucleotides that aren't necessarily limited to exon-skipping, or limited to DMD therapy?

I just want to -- I'm trying to understand the scope of -- putting the Roche Agreement aside, the scope of the other documents, or the other licensing information that you're looking for.

MS. VENEGAS: Certainly, and just to be clear, we are not looking for all of Sarepta's licenses generally that its company holds. We are looking for licenses related to the treatment of -- or for therapies for the treatment of Duchenne Muscular

Dystrophy, which was one of several therapeutic categories that Sarepta is focused on.

So we have limited our inquiry to licenses only for that therapeutic category, not all of Sarepta's licenses.

SPECIAL MASTER: Thank you, Counsel. I think I want to hear from Sarepta, if you want to respond to the opening argument from Nippon Shinyaku.

MR. O'QUINN: Thank you, Special Master. Ryan O'Quinn for Sarepta and UWA. Counsel's representation that they're not seeking all licenses that Sarepta holds is a little bit of a red herring, because the only products Sarepta has on the market are therapies directed to Duchenne Muscular Dystrophy.

These two parties are direct competitors from one another. Some of this business information is extremely sensitive.

And so we believe that the case law holds that in terms of the burden -- N.S. has to show at this point in the case -- they have to show that this isn't just a fishing expedition, and that they have reason beyond simple innuendo to believe that these are relevant documents.

Now to be clear, we have not withheld

relevant licenses. In fact, when we received letter correspondence from N.S. in October of 2022, the scope of the dispute -- and it's in our paper -- was exon-skipping oligonucleotide licenses for the treatment of Duchenne Muscular Dystrophy.

And it enumerated several licenses in a parenthetical. All of those licenses have since been produced. There is the separate disagreement about the Roche Agreement. But in terms of exon-skipping DMD licenses, which is what this case is about -- it's what the patent says you observe to cover. It's what the products are.

Those licenses are already in N.S.'s hands, and have been for months. It wasn't until May that the scope of this suddenly exploded into all DMD therapies. And in our view, based on the use of "and/or" in their briefing, all therapies directed to antisense oligonucleotides generally.

And there really -- you know, we never, kind of, saw this coming. This was not how the parties had been operating in their disputes up until this point. On April 4th, we understood ourselves to be at an impasse on the Roche Agreement and the redactions thereto.

But I believe there was no other dispute pending on licenses. Now, you know, as coincidentally, Sarepta awaits an FDA decision on a gene therapy product, we suddenly are seeing a sudden interest in other licenses.

And we think what's also telling is, you know, in a separate case involving Sarepta -- but that also involves Counsel for N.S., before Judge Andrews in this district, they delineated these licenses -- especially with respect to the Roche Agreement -- that exon-skipping licenses and gene therapy licenses simply weren't relevant to one another, and we believe that opinion should hold here as well.

SPECIAL MASTER: Counsel, I have a -- I'll interrupt just to ask a question. I think -- can you address this issue as to whether or not -- why is this information not relevant to this issue of comparable licenses?

And I think there's some case law that Moving Counsel cited in the papers that suggest that even for comparable licenses, these issues can be -- they don't necessarily have to be the same technology. Could be a related technology.

So it doesn't necessarily have to be narrowly tailored to just the accused product, or the technology of the patents in suit. Can you address that issue? The comparable licenses issue, as part of the reasonable royalty analysis?

MR. O'QUINN: Thank you, Special Master. Part of what it -- we think that -- you know, I read that case law as well, and I concede that's there. I think that has to be read in conjunction, first of all, with the purpose of what this is, which is, again, a Georgia-Pacific Reasonable Royalty Analysis.

And that relates to royalties received, and rates paid. [redacted]

And also the comparability analysis is part and parcel with the proportionality requirement of Rule 26(b)(1). The burden here on Sarepta would be significant. There simply isn't proportionality to the case, especially this late in discovery.

And the sensitivity of the business between the parties is a factor that should be

considered in that proportionality. These two competitors right now are the only companies, to my understanding, that have exon-skipping therapies for DMD in the marketplace.

And so that is a factor that needs to be weighed in before we even get to the comparability analysis.

SPECIAL MASTER: Also, Counsel, I just want to circle back to another question -- and this is Counsel for Sarepta -- the issue of just that Roche document.

It seems like that that document was produced, and even according to the briefing, was within the scope of, I guess, what -- I guess you're saying you understood the scope of the licenses to be narrowed to.

I guess help me understand, or can you explain, kind of, the justification for the redactions and not -- and what's the basis -- I think I understand Counsel's briefing in that regard -- opposing Counsel's briefing to be -- trying to figure out the basis for the redactions to that Roche Agreement.

MR. O'QUINN: Thank you, Special

Master. The Roche Agreement is a larger omnibus agreement for a large bouquet of rights. And what they are is rights that are all outside the United States, which we have not understood to be the scope of this case.

They impact a wide variety of therapies. Not only just the exon-skipping therapies for DMD we've been talking about. Not only the gene therapy that we've been talking about, but other technologies, and other mechanisms of action that simply aren't germane to this case at all.

And due to the sensitivity of those terms and the fact that they cover different therapies -- different territories -- we've kept the terms that don't relate to this case under wraps due to the sensitivity of the party's business relationship.

And Judge Andrews endorsed that in the Regenxbio case, allowing some of those terms to remain redacted.

SPECIAL MASTER: And just to be -- in that case, did Judge Andrews do an in camera review of the redactions and then rule as to what redactions stayed, and what redactions were maintained or not

maintained?

MR. O'QUINN: That's correct, Special Master.

SPECIAL MASTER: And I think I'll give Nippon's Counsel an opportunity to respond -- to have the last word on this issue, and then we can move to the next issue, if you have any further comment?

MS. VENEGAS: Yep. Thank you. I appreciate that. And just a few quick comments here. Obviously, we're in the context of federal court litigation between competitors. So the fact that we are competitors alone should not be a basis for withholding relevant information in this case.

We are entitled to more than what it is in the public domain to zealously advocate our case, and our experts should be entitled to have this information to conduct their work in this case.

We have a protective order in place in this case that allows for production of information at the attorney's eyes only level which will allow our expert access to this information. And frankly, if it's not relevant, they're not going to use it in their analysis.

And I think that is really the standard

by which this information should be viewed. With respect to the redactions in the Roche agreements, we find them completely unacceptable.

But because to understand how all the parts of the agreement work together, we need full access to the entire agreement. We can't have just the pieces of the agreement that Sarepta chooses, you know, to pick and choose to give to us for our expert to evaluate.

So we don't believe any of the redactions are appropriate. If the agreement's relevant, the entire agreement should be produced. Also, as to burden, I really haven't heard a burden argument from Sarepta, other than the fact that these two companies are competitors, which, again, is not a unique situation.

And there is no burden here. This is a handful of, you know -- well, first of all, the production of the Roche Agreement -- there's no burden.

And these other few handful of agreements that relate to genetic therapy for DMD -- it's a small number of agreements, which again, can be produced under attorney's eyes review only.

In terms of the -- your point which you made about the comparability of these licenses -- that's exactly correct. They need not be the exact same technology. They can be related technologies.

And in fact, N.S., our client, has produced a license related to a cell-based therapy, which is a different type of technology, which is not exon-skipping because in our view, that is within the scope of a potentially comparable license that experts should be able to see and evaluate in this case because it is for the treatment of Duchenne Muscular Dystrophy. And so we --

SPECIAL MASTER: But Counsel, just -- doesn't Sarepta say that that license is irrelevant; right? Their position is that license was kind of just voluntarily submitted late in discovery, and it's really irrelevant. It's one document that's seemingly irrelevant.

MS. VENEGAS: Well, they --

SPECIAL MASTER: -- produced, I guess it goes to the proportionality issue -- their position is that it's irrelevant; right?

MS. VENEGAS: And they have -- they requested that we provide that document, and we did.

CERTIFICATE OF DEPOSITION OFFICER

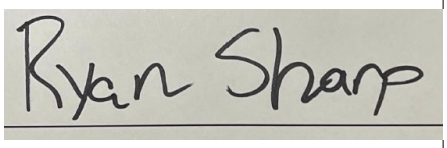
I, ANDREW WEADER the officer before whom the foregoing proceedings were taken, do hereby certify that any witness(es) in the foregoing proceedings, prior to testifying, were duly sworn; that the proceedings were recorded by me and thereafter reduced to typewriting by a qualified transcriptionist; that said digital audio recording of said proceedings are a true and accurate record to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

Andrew Weader

ANDREW WEADER
Notary Public in and for the
State of Delaware

CERTIFICATE OF TRANSCRIBER

I, RYAN SHARP, do hereby certify that this transcript was prepared from the digital audio recording of the foregoing proceeding, that said transcript is a true and accurate record of the proceedings to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.



RYAN SHARP

APPENDIX
326-333

EXHIBIT J

Morgan Lewis

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October 31, 2022

VIA E-MAIL

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Re: *Nippon Shinyaku Co., Ltd. v. Sarepta Therapeutics, Inc.*, C.A. No. 21-1015 (GBW)

Dear Aaron:

We write in response to your September 26, 2022 letter and the parties' additional discussions during the August 1, 2022 meet and confer. Should there be any outstanding issues, we request a meet-and-confer this week.

I. UWA, the UWA Inventors, and Core Agreements

During our August 1, 2022 meet-and-confer, we inquired regarding what information, if any, Sarepta has relating to the representation of UWA and the UWA inventors, and the scope of UWA information to which Sarepta has access. Your team refused to provide any information about the representation of UWA and the UWA inventors at that time, but assured us that Sarepta would provide this information in connection with its Initial Disclosures later in August. Sarepta's eventual disclosures, however, neglected to even mention the UWA inventors as individuals who may have relevant information, much less specify information regarding their representation and contact information known to Sarepta. We have followed up multiple times, but have not yet received any clarification from Sarepta on these issues.

There is no excuse for Sarepta's failure to provide whatever information it had regarding UWA and the UWA Inventors to date in its Initial Disclosures. And we do not understand why it has taken almost three months for Sarepta to answer a simple question regarding the representation of UWA and its inventors, particularly given Sarepta's ongoing licensing relationship with UWA. Accordingly, please confirm that by **Friday, November 4, 2022** that Sarepta will (1) supplement its Initial Disclosures with any information it has

by that date regarding the representation of and contact information for UWA and the UWA inventors; and (2) to the extent Sarepta's inquiry into these issues is not complete by that time, provide an explanation regarding why the inquiry remains unresolved (*e.g.*, a non-responsive witness). If Sarepta is unable to identify counsel for the UWA and the UWA inventors by November 4, 2022, NS will seek testimony and documents directly from them.

Additionally, while NS has produced core agreements with NCNP and NS Pharma relating to Viltepso®, we have not seen like documents from Sarepta. Please confirm that Sarepta will produce at least the following "core" agreements by **Friday, November 4, 2022**:

- All agreements/licenses related to developing exon-skipping oligonucleotides and/or Vyondys53® (including Sarepta's agreements with UWA, Biomarin, Roche and Royal Holloway), and any related consulting agreements (*e.g.*, with the UWA inventors);

- All agreements with any third party manufacturers of any component of Vyondys53® or third parties involved in its formulation and fill (including agreements with [redacted]);

- All agreements with any third parties who assist with distributing Vyondys53® (including agreements with home care providers such as [redacted]).

II. Production of Regulatory and Clinical Trial Documents

NS is interested in reaching agreement regarding the scope of regulatory and clinical documents for production, but would not agree to Sarepta's recent proposal (as stated in your September 26, 2022 letter). As discussed below, we propose that, in addition to particular NDA sections, the parties produce certain formal reports to FDA and FDA correspondence. Targeting these formal reports and correspondence that should provide the parties information about clinical trials without jeopardizing their scientific integrity and allow the parties to ascertain whether additional documents regarding particular regulatory events are necessary.

Please let us know if you are amenable to NS's proposal on this issue.

A. The Parties' NDAs

Provided Sarepta agrees with NS's proposals on regulatory and clinical trial documents, NS can agree to the general scope of NDA sections Sarepta has proposed for disclosure:[1]

[redacted]

Because NS's manufacturing process is not at issue in this litigation, however, we reserve the right to withhold irrelevant material relating thereto from any NDA sections produced.

In addition to these sections, we request that Sarepta additionally provide sections of the NDA sufficient to show [redacted] for the steps accused of infringing the claimed manufacturing methods of the '322 Patent, as well as the steps preceding and following the accused steps. We expect that information may be relevant to infringement under the doctrine of equivalents.

[1] From reviewing NS's NDA for Viltepso® against similar sections Sarepta has produced, it appears that the parties may have organized or titled certain sections or subsections slightly differently. As we understand your reference to particular subsections to be based on the numbering/titling of Sarepta's NDA, NS may ultimately produce differently-titled subsections that we understand to be the equivalent of those specified in our correspondence.

B. Other Regulatory and Clinical Trial Information

NS agrees that patient-identifying information may (and should) be redacted before production but does not agree that individualized data from clinical trials and post-marketing data (*e.g.*, safety/adverse event information) should be withheld. We propose that the parties produce at least the following documents and formal correspondence with FDA:

- Any final clinical study reports for the accused products;
- Any interim clinical study reports for the accused products;
- Any publications/posters for clinical trial results for the accused products;
- Investigator's brochures provided in connection with clinical trials for the accused products;
- Annual clinical trial reports to the FDA involving the accused products; and
- Any pre- or post-marketing reports to the FDA regarding safety/adverse events and/or distribution of the accused products (*e.g.*, free drug accounting);
- Cover letters for the parties' original NDA submissions, any amendments/supplements relating to the particular NDA sections specified in Section A above, and any FDA responses thereto;
- Cover letters for annual and other reports to the FDA and any FDA responses thereto;
- Formal correspondence with the FDA relating to approval status, including Complete Response Letters, formal approval notices, and any responses thereto.

It is our understanding that at any points where these documents provide individualized patient data, they would use patient codes, and would lack patient-identifying information.

III. Searching for Prosecution-Related Documents and Searching Legal Personnel Files

During our August 1, 2022 meet-and-confer, we briefly discussed the scope of discovery into patent prosecution and the parties' obligations to search their legal personnel's files (which we understood to encompass attorneys, patent agents/paralegals/other specialists, and their administrative staff) for responsive documents.

From reviewing the parties' response to requests for production relating to patent prosecution efforts, it appears that neither Sarepta nor NS have agreed to produce documents relating to patent prosecution efforts beyond the certified file histories for each asserted patent. Provided that the parties also conduct a reasonable search for and produce any other substantive communications with the PTO regarding prosecution of the asserted patents (*e.g.*, slide decks presented during examiner interviews), we would be willing to formalize this seeming agreement into a stipulation that producing the certified prosecution histories has satisfied each party's obligation to search for and produce documents relating to their efforts to prosecute the asserted patents.

IV. Production of Exon-Skipping Testing Data

From the parties' correspondence to date, we understand each to assert proportionality objections to the other's requests for documents relating to exon 53-related exon skipping testing. *See, e.g.*, Sikora Ltr. (Jul. 6, 2022) ("NS does not see the relevance of experimentation performed after the filing of PCT/JP2011/070318, to which all asserted NS Patent claim priority, such that the requested discovery is unduly broad, overly burdensome, and disproportionate to the needs of the case."); Clay Ltr. (Jul. 26, 2022) at 14-15 (stating that Sarepta intended its response to NS's requests "generally directed to the research and development of oligonucleotides for inducing skipping of exon 53 of dystrophin pre-mRNA" to include only "the golodirsen drug substance and the drug product, Vyondys 53®"). Provided Sarepta confirms that it has possession, custody, or control over the UWA inventors' work and will produce it (along with any other exon 53-related testing data from third parties that may be in its possession, custody, or control), NS believes the parties can reach agreement regarding the scope of exon-skipping testing data for production.

It is our understanding that both parties had exon-skipping therapy products under development concurrently with their development of the accused products and have since continued efforts to develop exon-skipping products other than the accused products. As such, NS remains convinced that producing exon-skipping data over an unlimited time period would not be proportional to the needs of this case, particularly given that reviewing NS's Japanese-language documents to, *inter alia*, exclude documents regarding these other products would be particularly onerous. That said, we have considered your comments regarding the purported relevance of post-priority date testing to the validity of the NS Patents and, in the interests of resolving this issue, would consider expanding the time period for which the parties must produce exon-skipping data.

To address both parties' proportionality concerns, we propose that <u>each party need only search for and produce documents relating to testing exon 53-directed oligonucleotides that was performed on or before the date that patient enrollment began for its first clinical trial for viltolarsen (NS) or golodirsen (Sarepta), as applicable.</u> We expect this limitation to capture the testing leading to all asserted patents and the development period that led to each parties' selection of the accused products (including any comparative testing that may have been performed for candidate selection), but to substantially exclude subsequent

development efforts for other exon-skipping products.[2] Please let us know if you are amenable to this proposal.

V. Schedule for Disclosing Core Financial Records

As previously discussed, we would like to reach agreement on core financial records regarding sales, manufacture, and distribution that the parties will begin disclosing. We propose that the parties begin by producing the following by **Friday, December 2, 2022**:

- documents sufficient to show gross sales (dollars and units), net sales (dollars and units), gross profit, operating profit, and cost of goods sold on a monthly or quarterly basis for the accused products;
- documents sufficient to show discounts applied in the calculation of net sales;
- documents sufficient to show costs applied in the calculation of cost of goods sold;
- documents sufficient to show other units manufactured in the United States or provided for use in the United States under circumstances other than a sale (*e.g.*, free drug and/or clinical trial participates);
- average sales price (ASP) reports to FDA; and
- profit & loss statements relating to the accused products.

In addition, because we understand Exondys51® to be prescribed to certain [redacted], we request that Sarepta produce the same documents for Exondys51®, which are relevant to the damages inquiry. These productions should, at minimum, allow the parties to identify whether (and what) additional financial records will be required.

Please let us know if Sarepta is amenable to this proposal.

[2] The extent Sarepta is concerned this would preclude other voluntary productions of other data that it believes bears on the validity of asserted patents, we confirm that we would not understand this proposal to bar Sarepta from voluntarily producing testing conducted after the specified date if it desires.

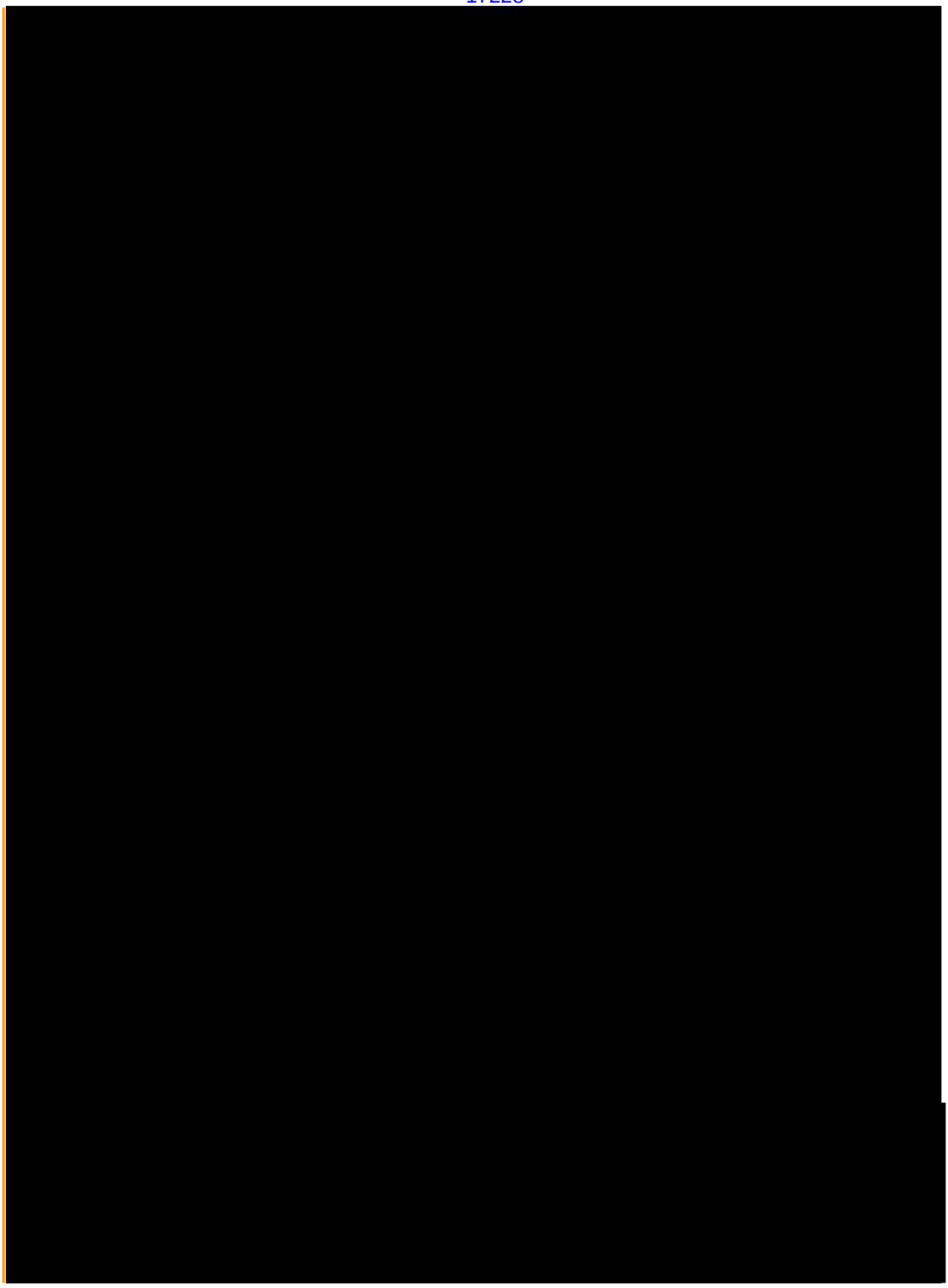
Sincerely,

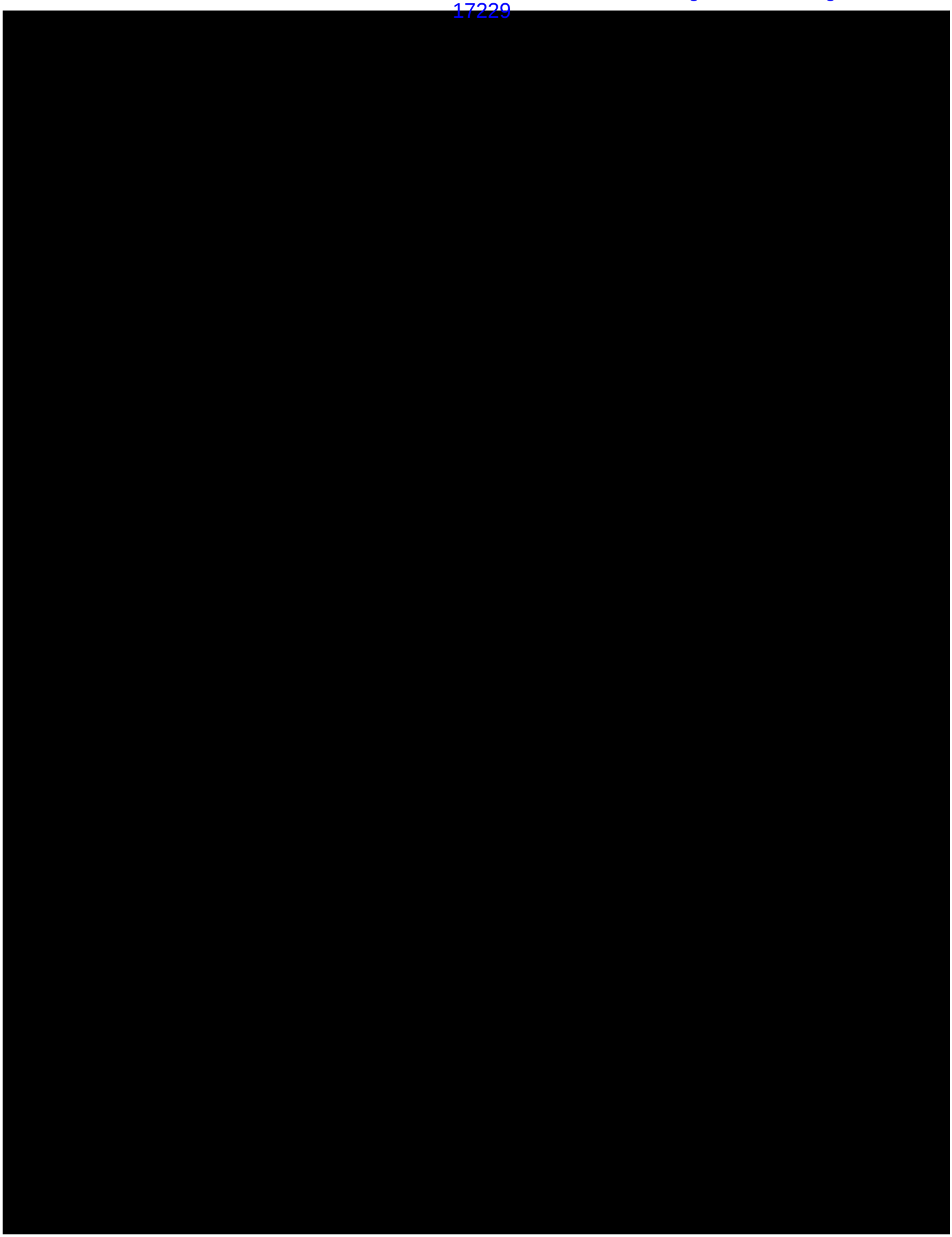
/s/ Mike Sikora

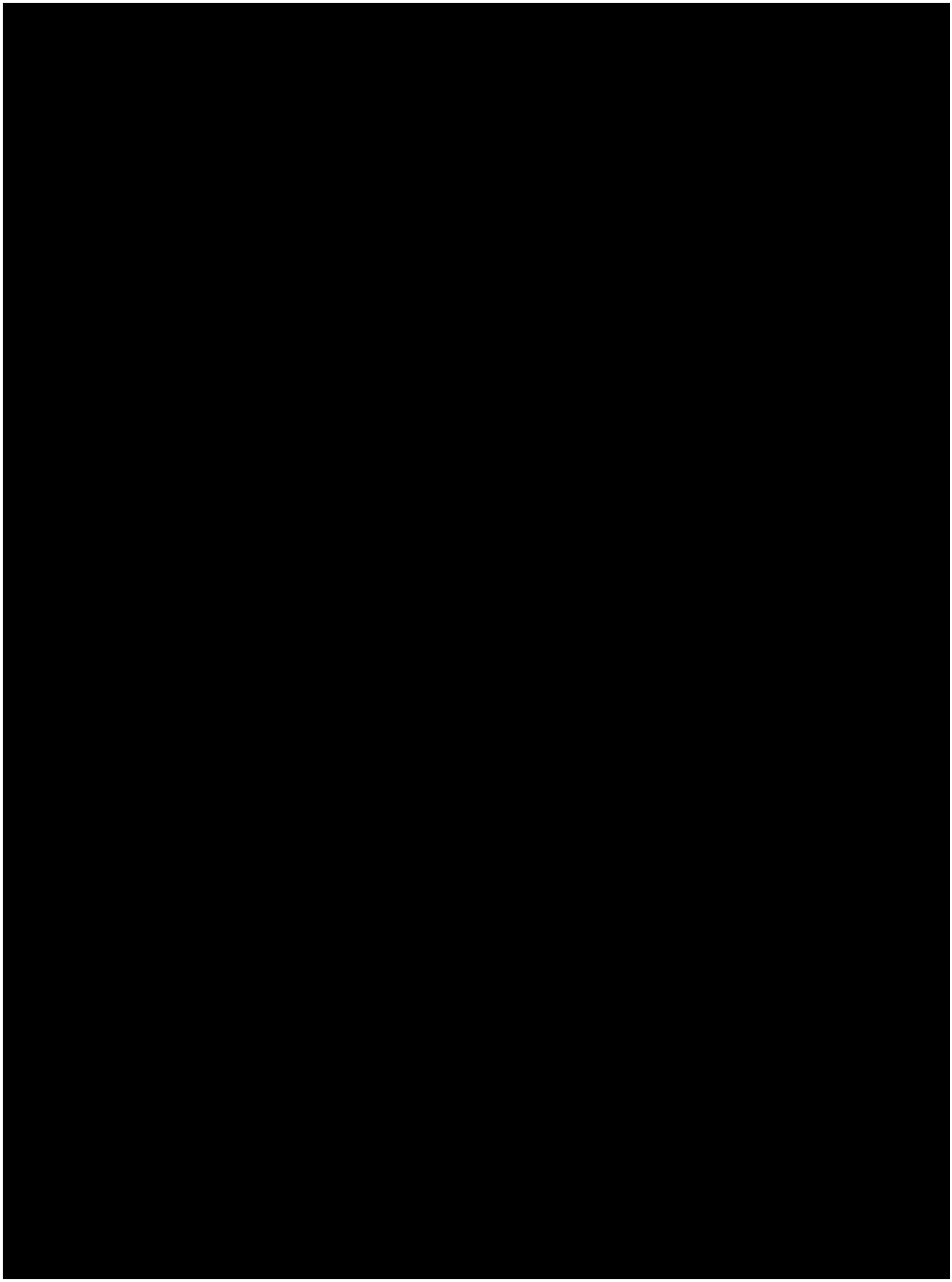
Michael T. Sikora

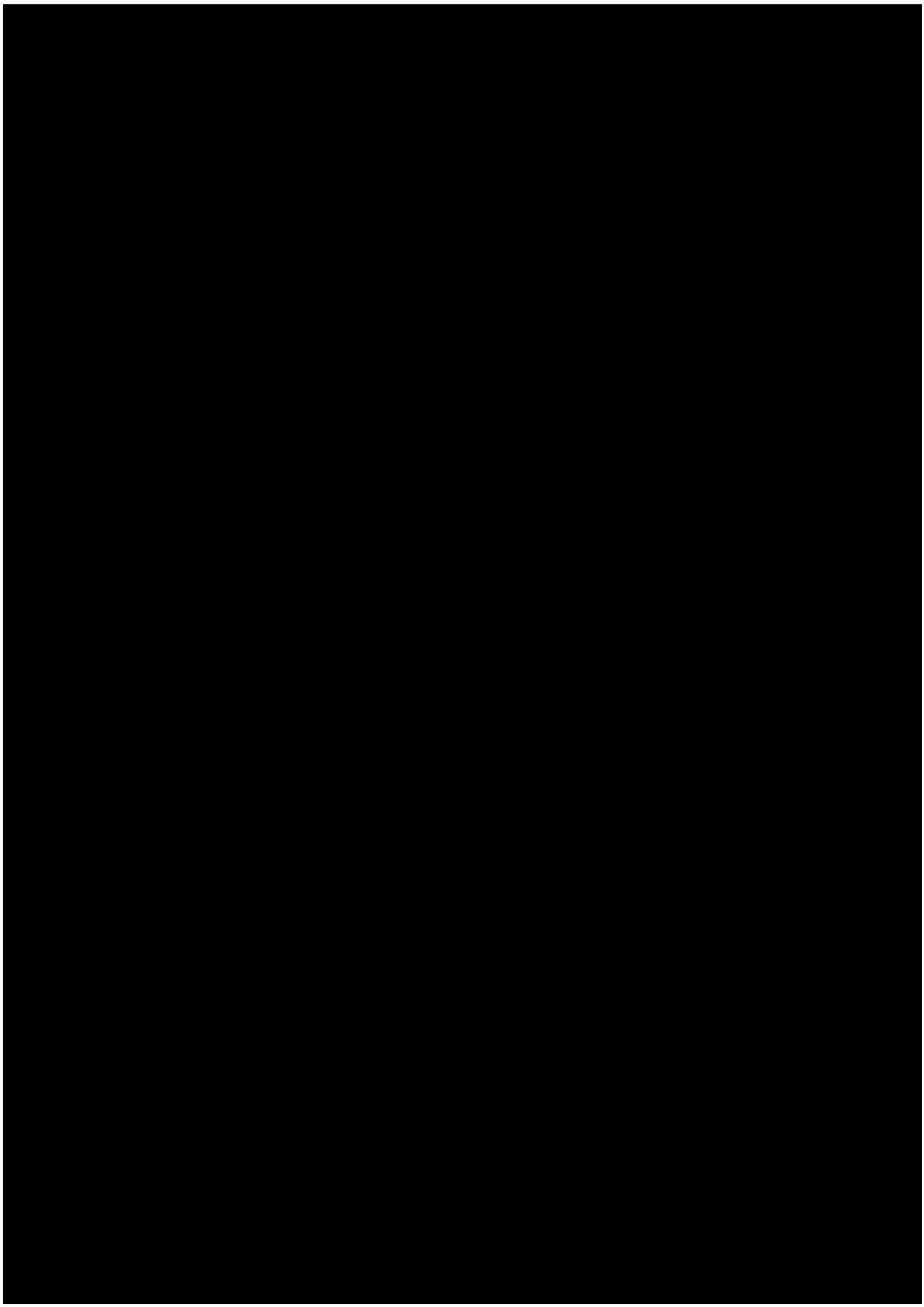
MTS

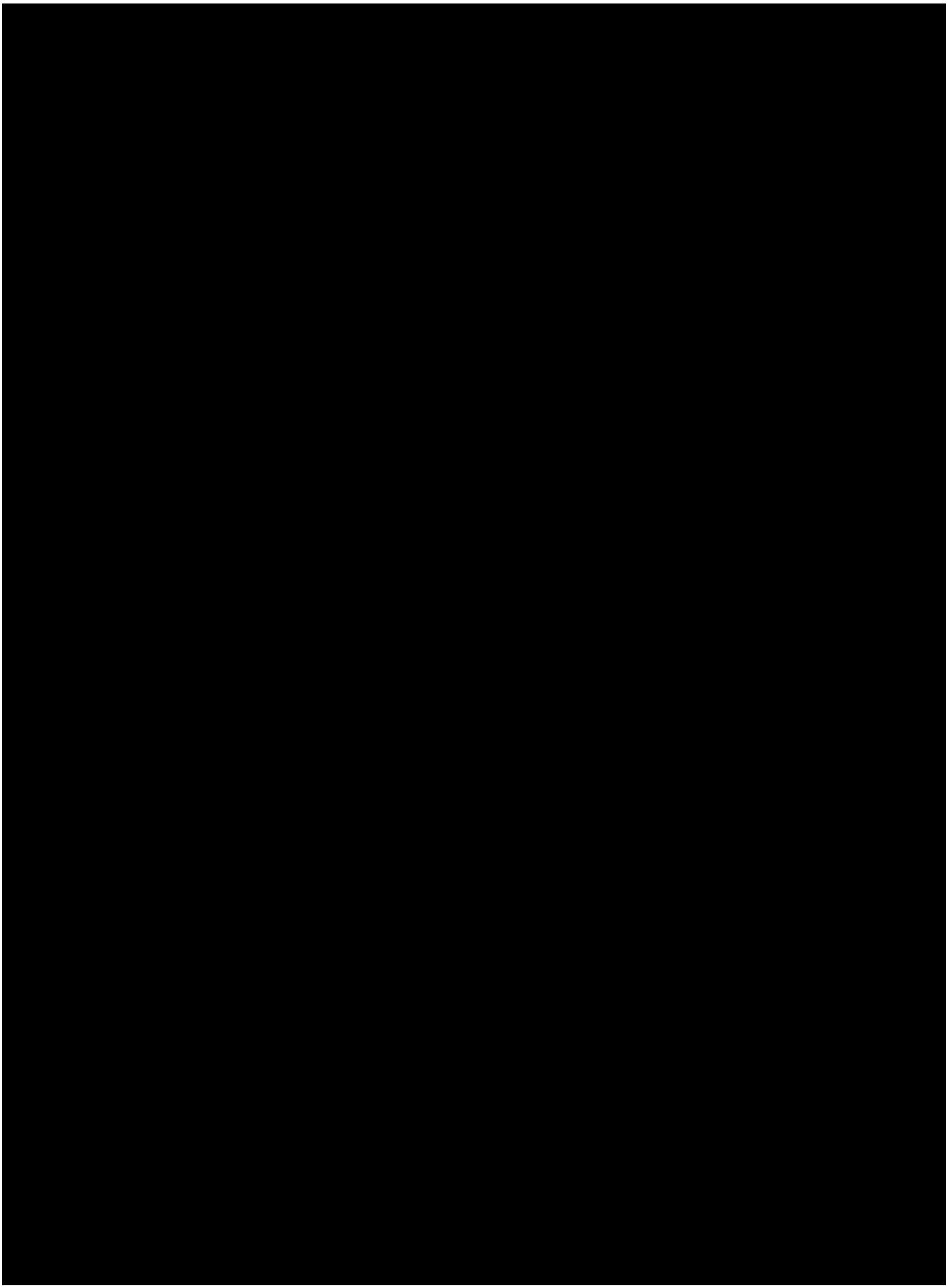
APPENDIX
334-351

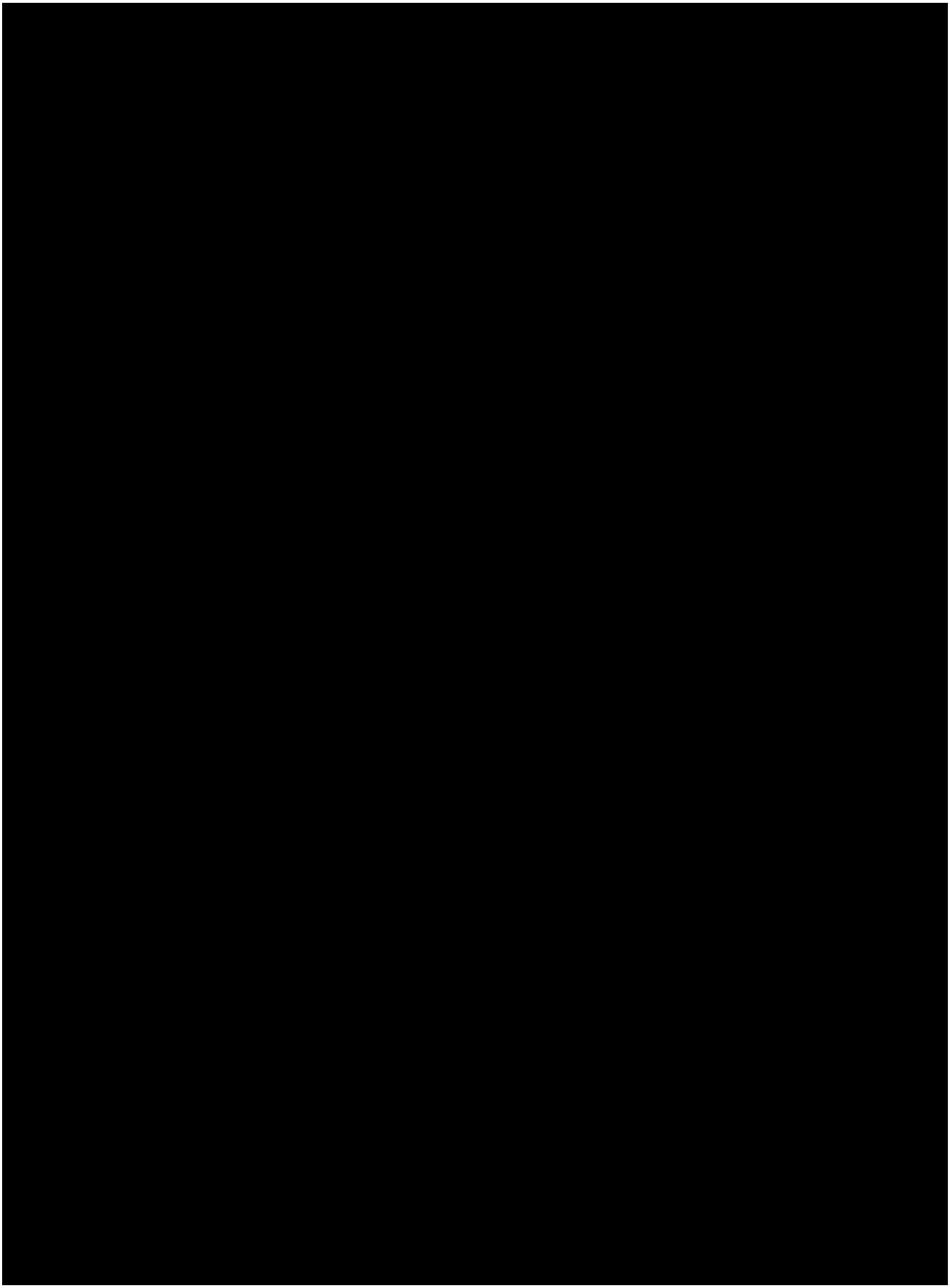


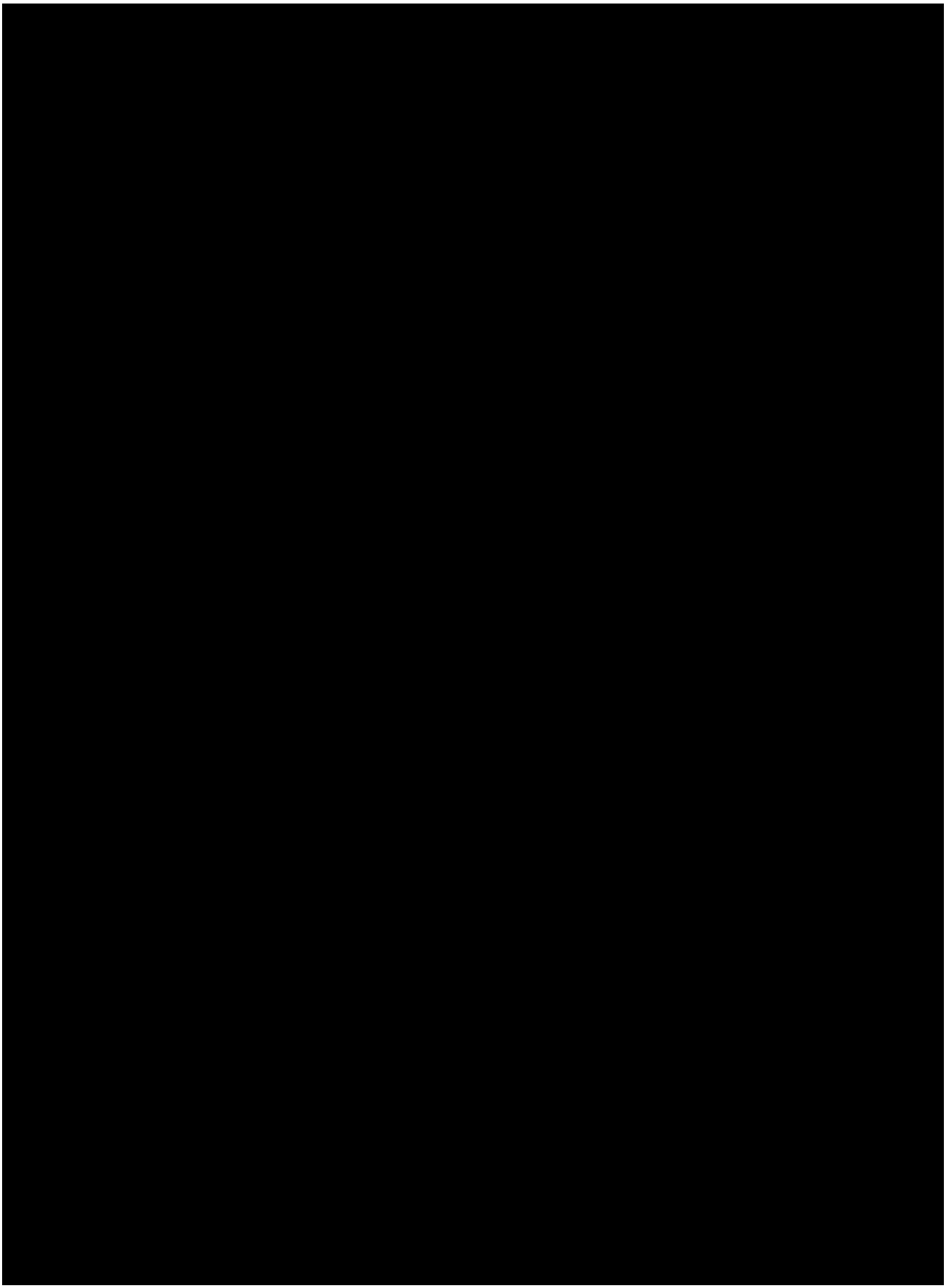


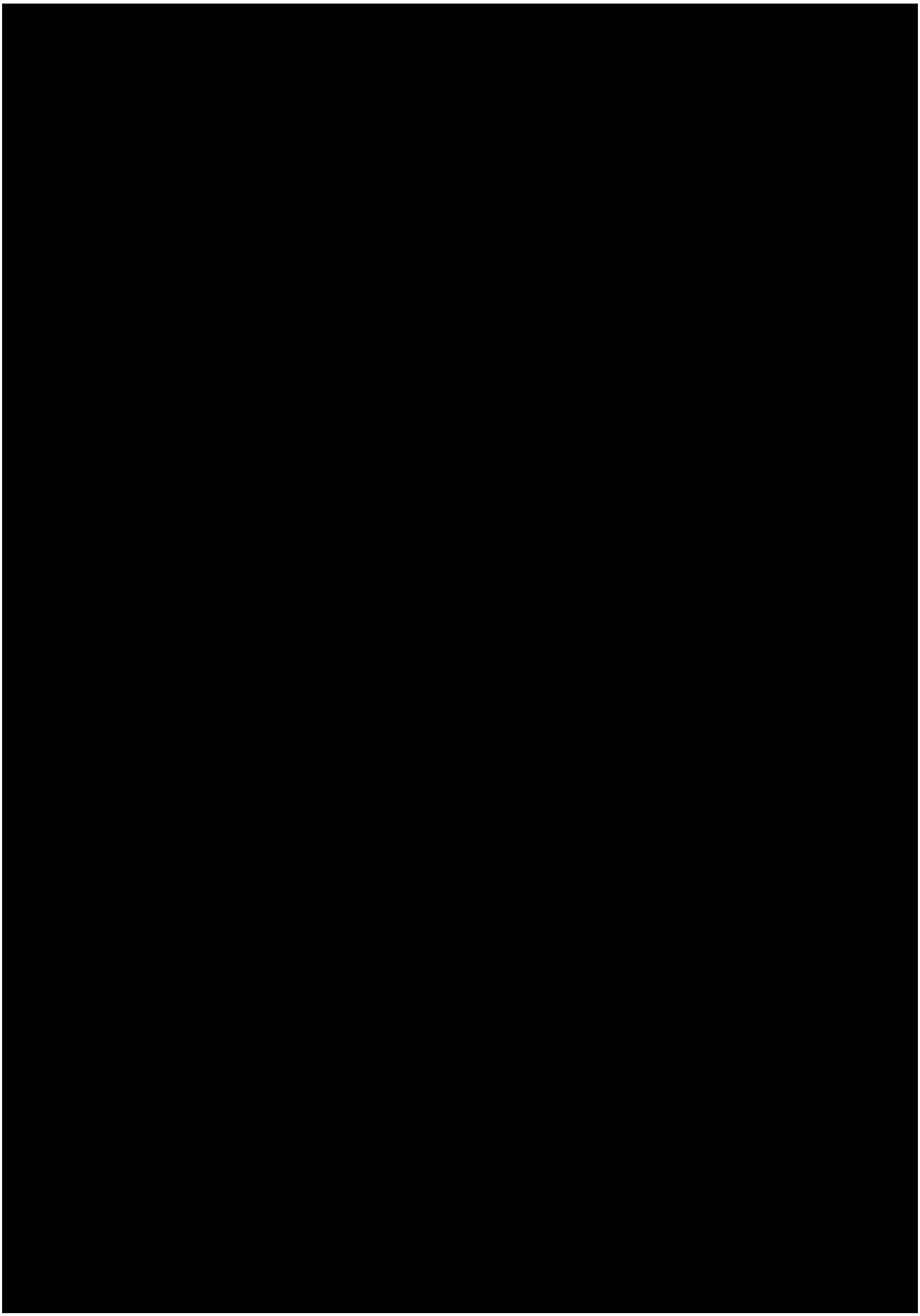


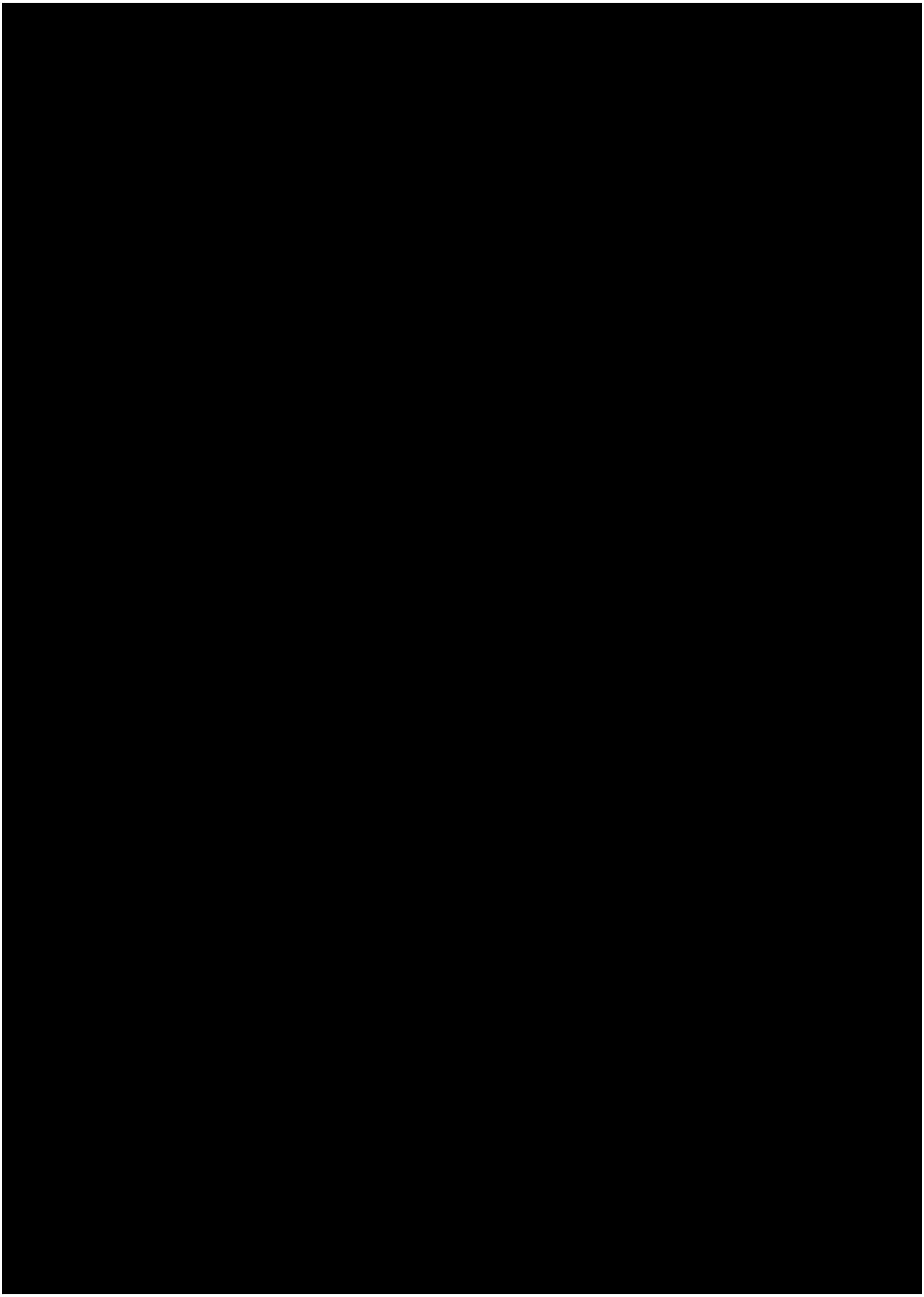


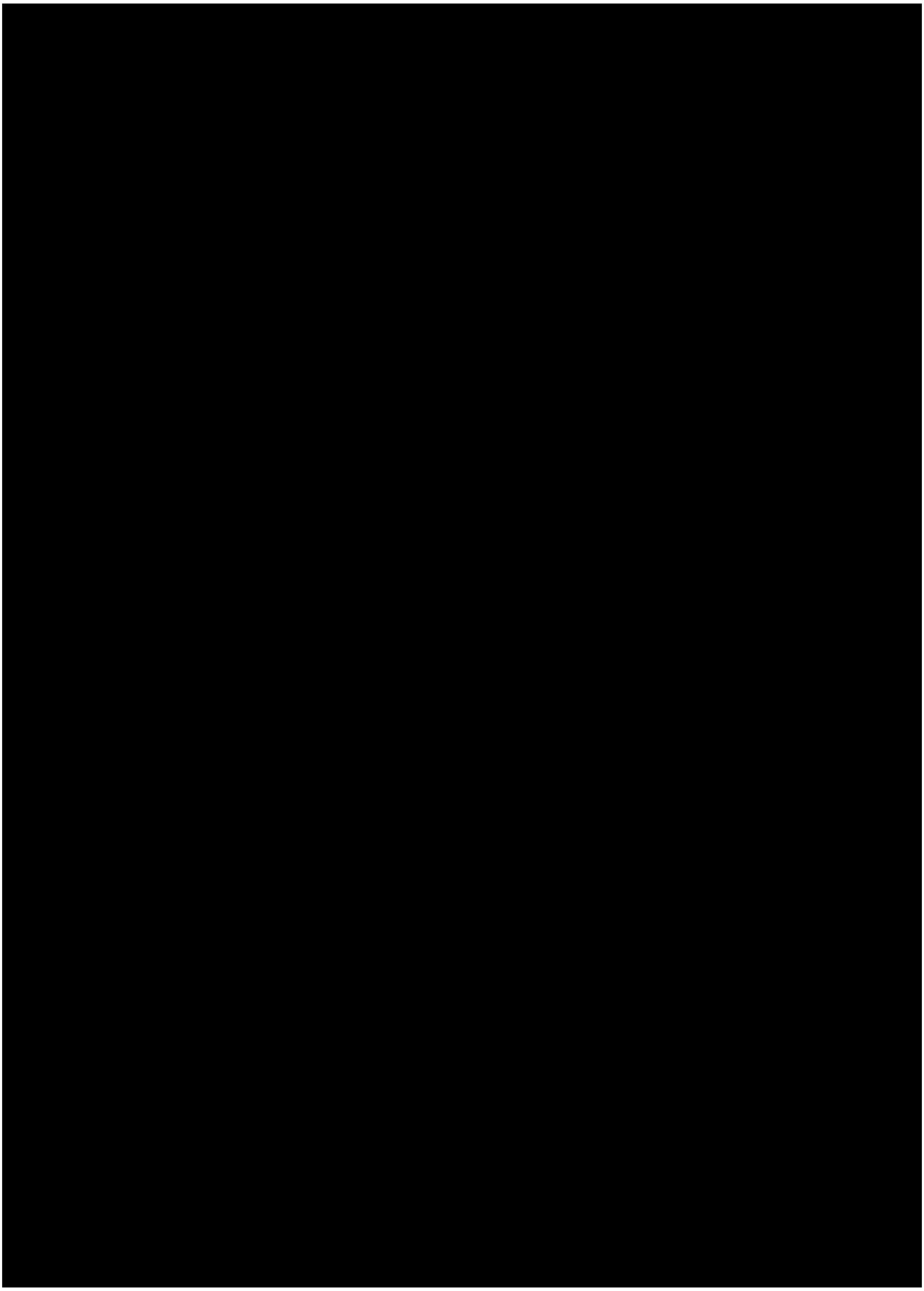


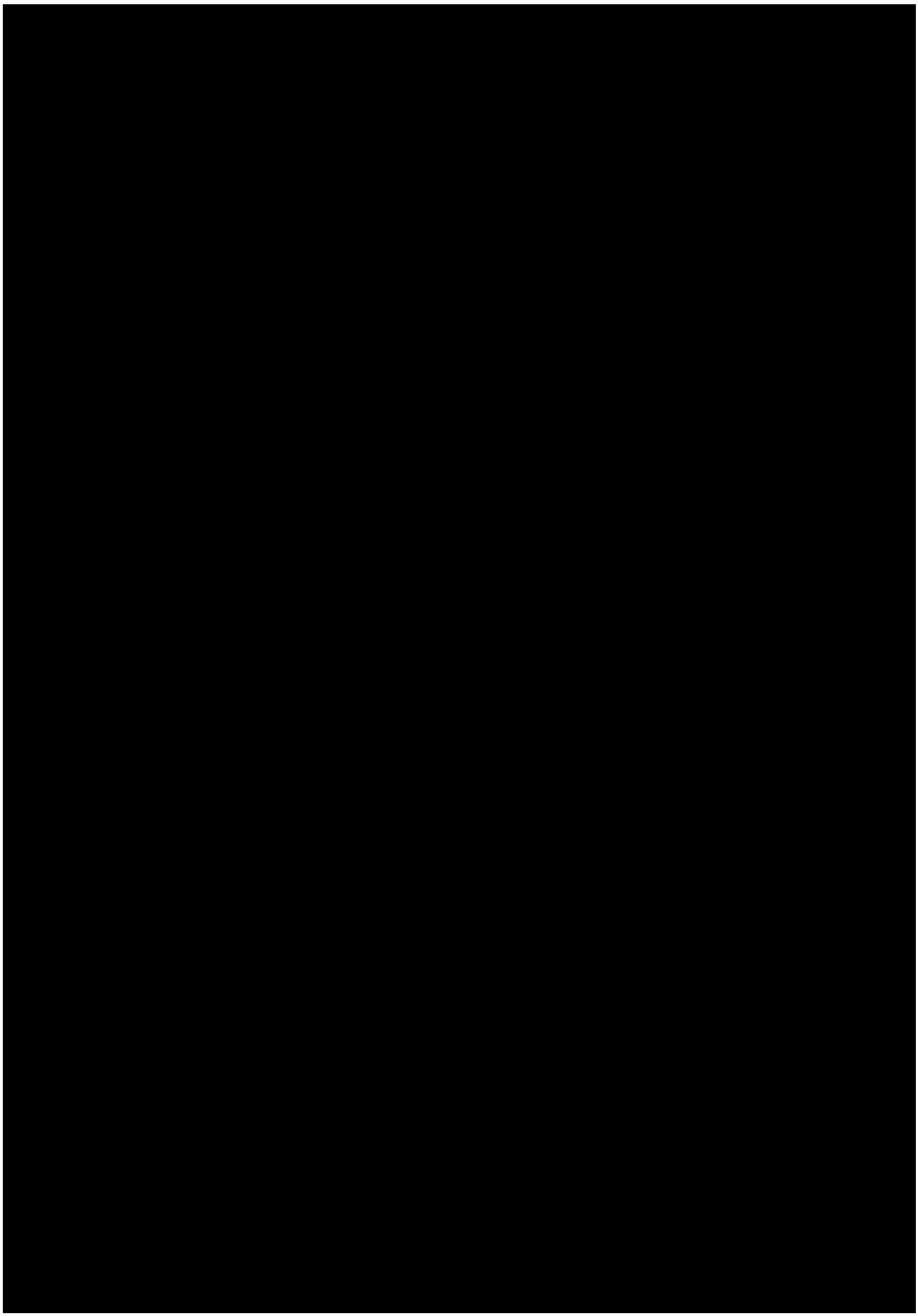


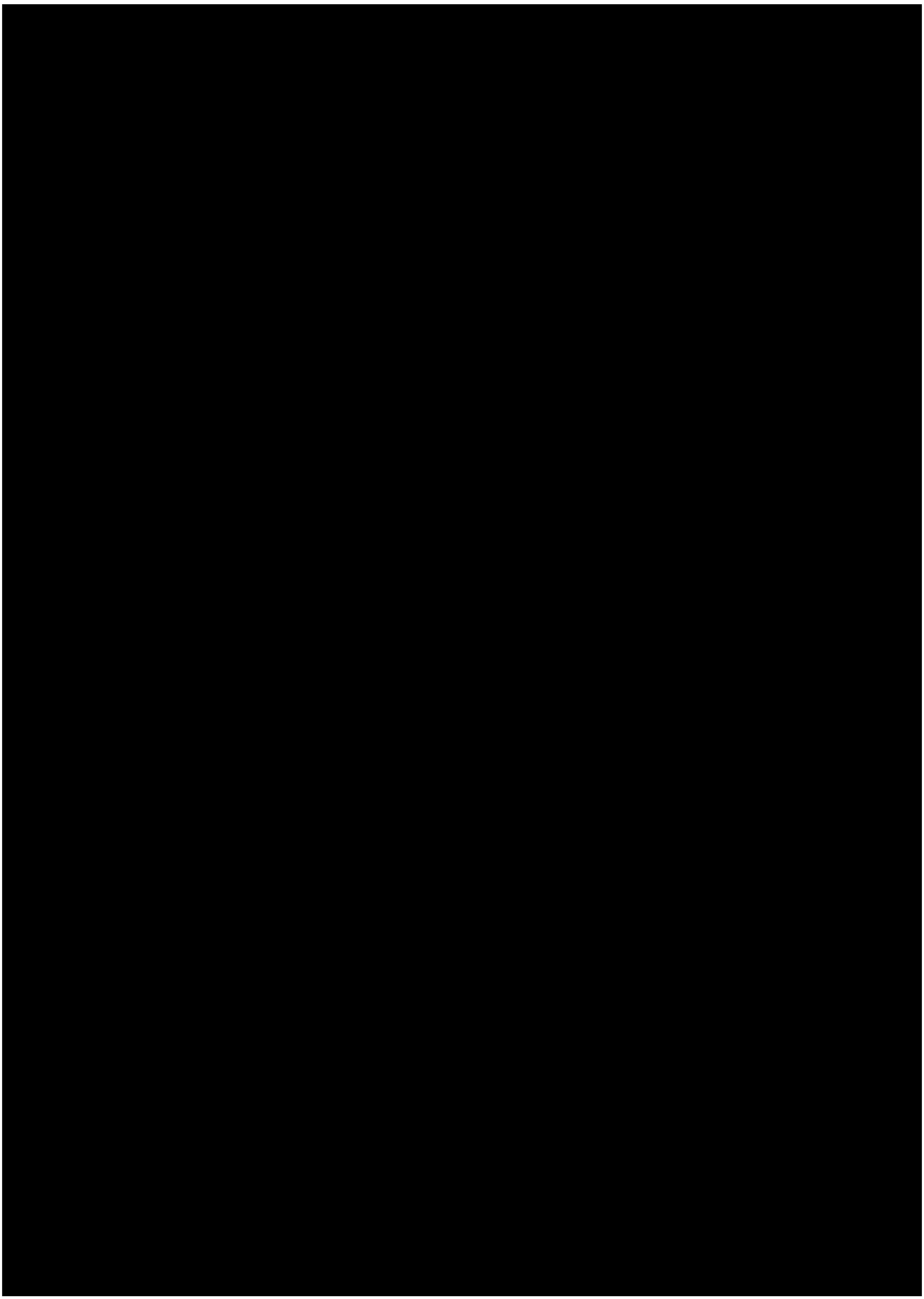


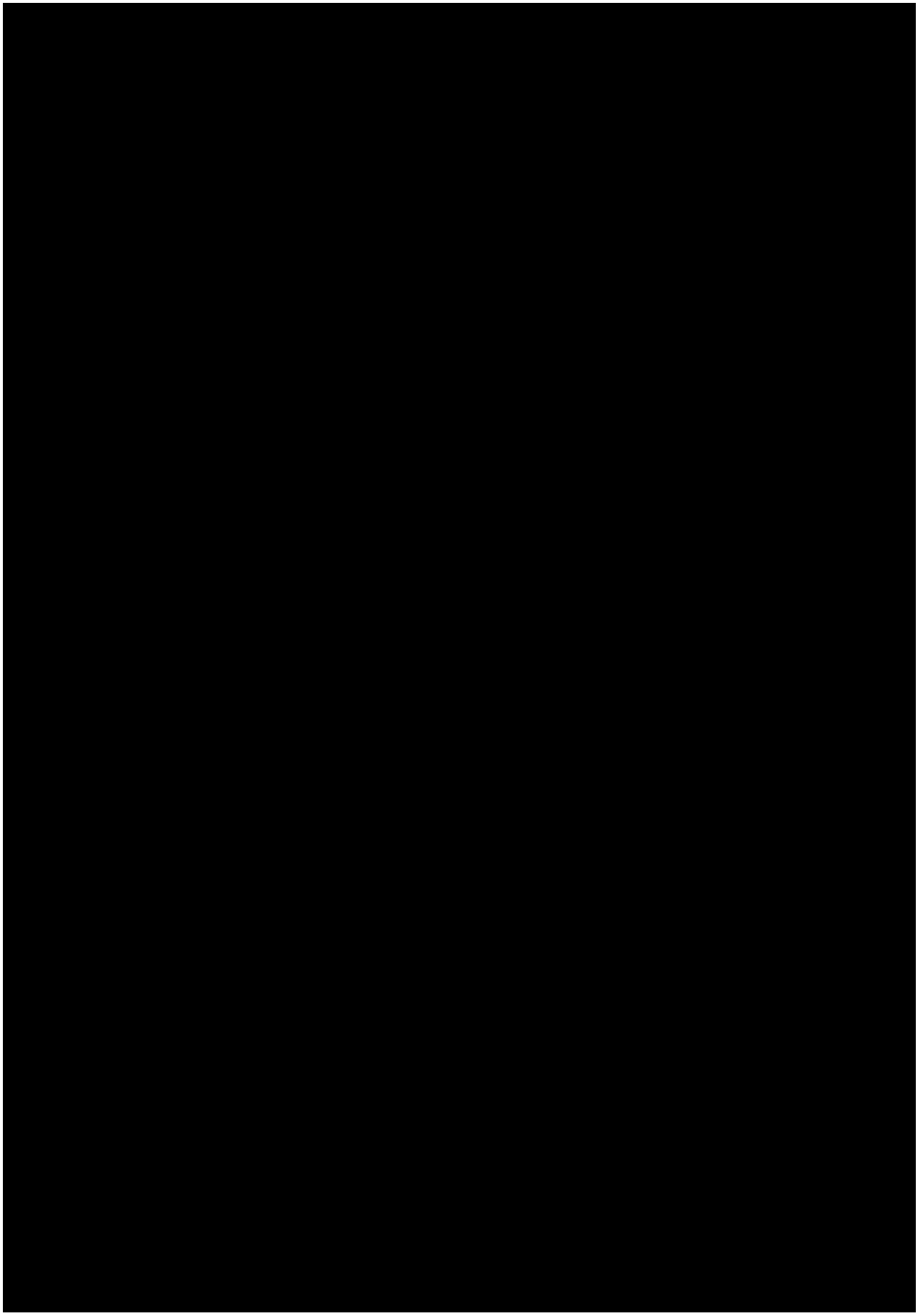


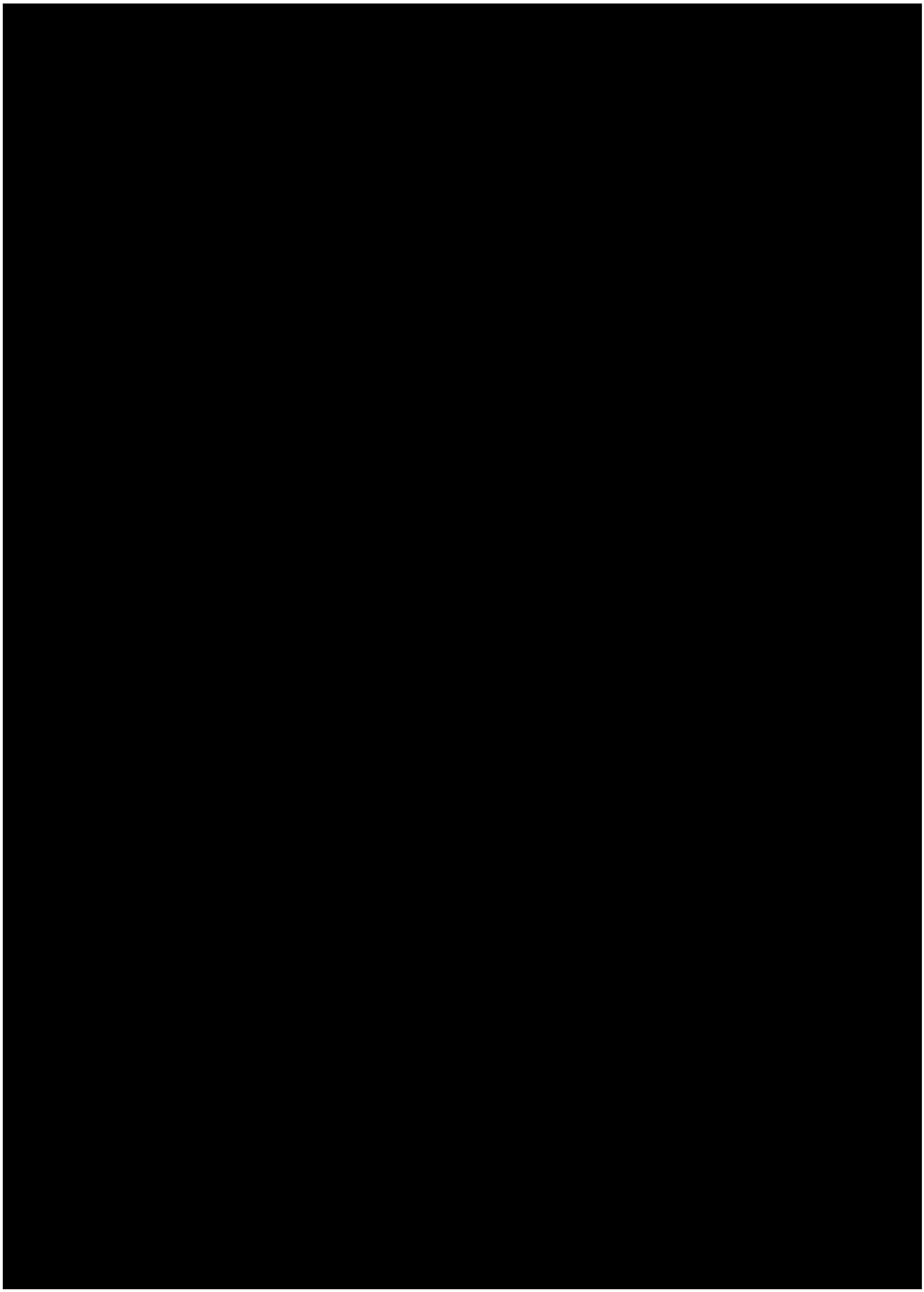


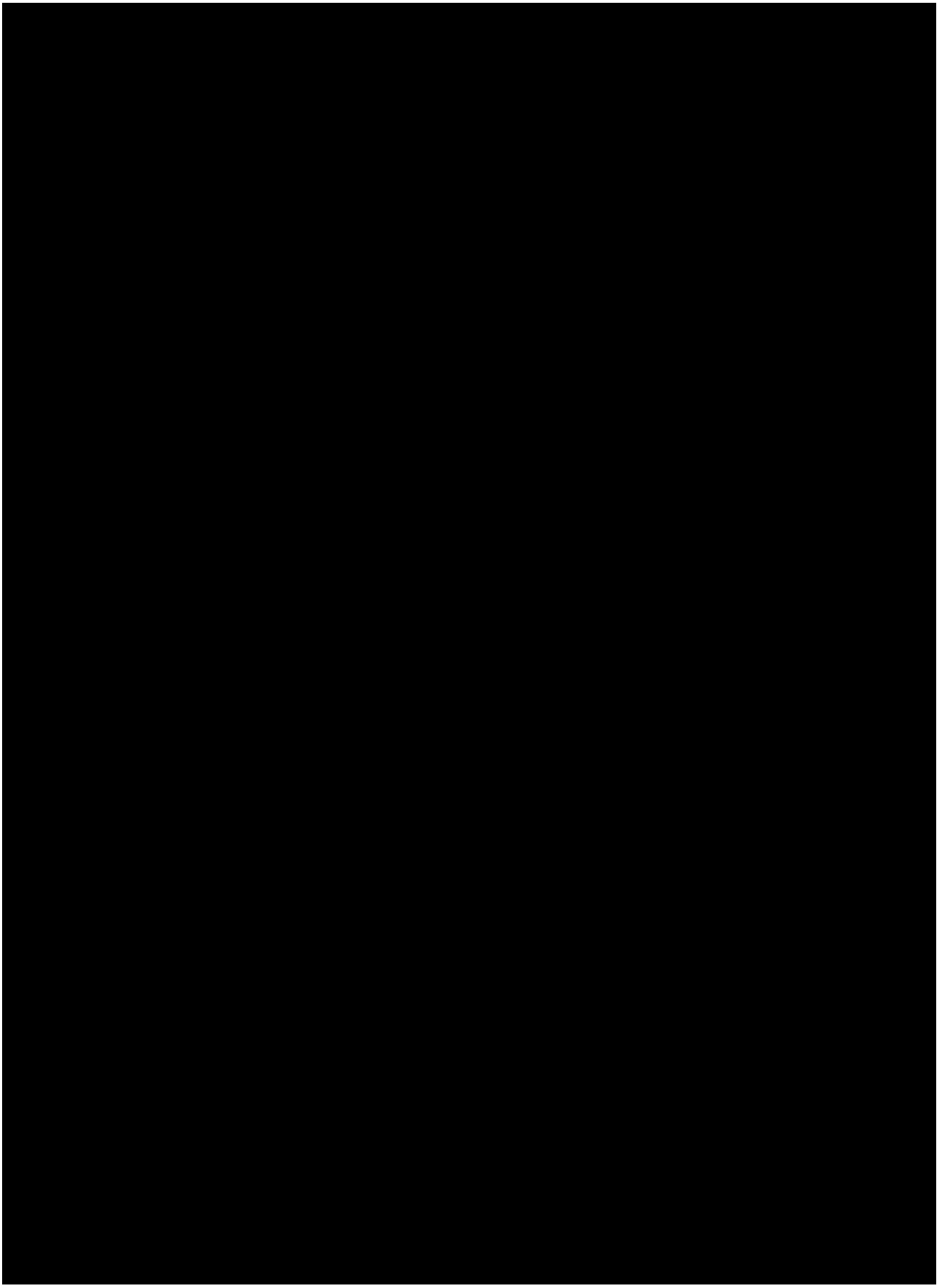


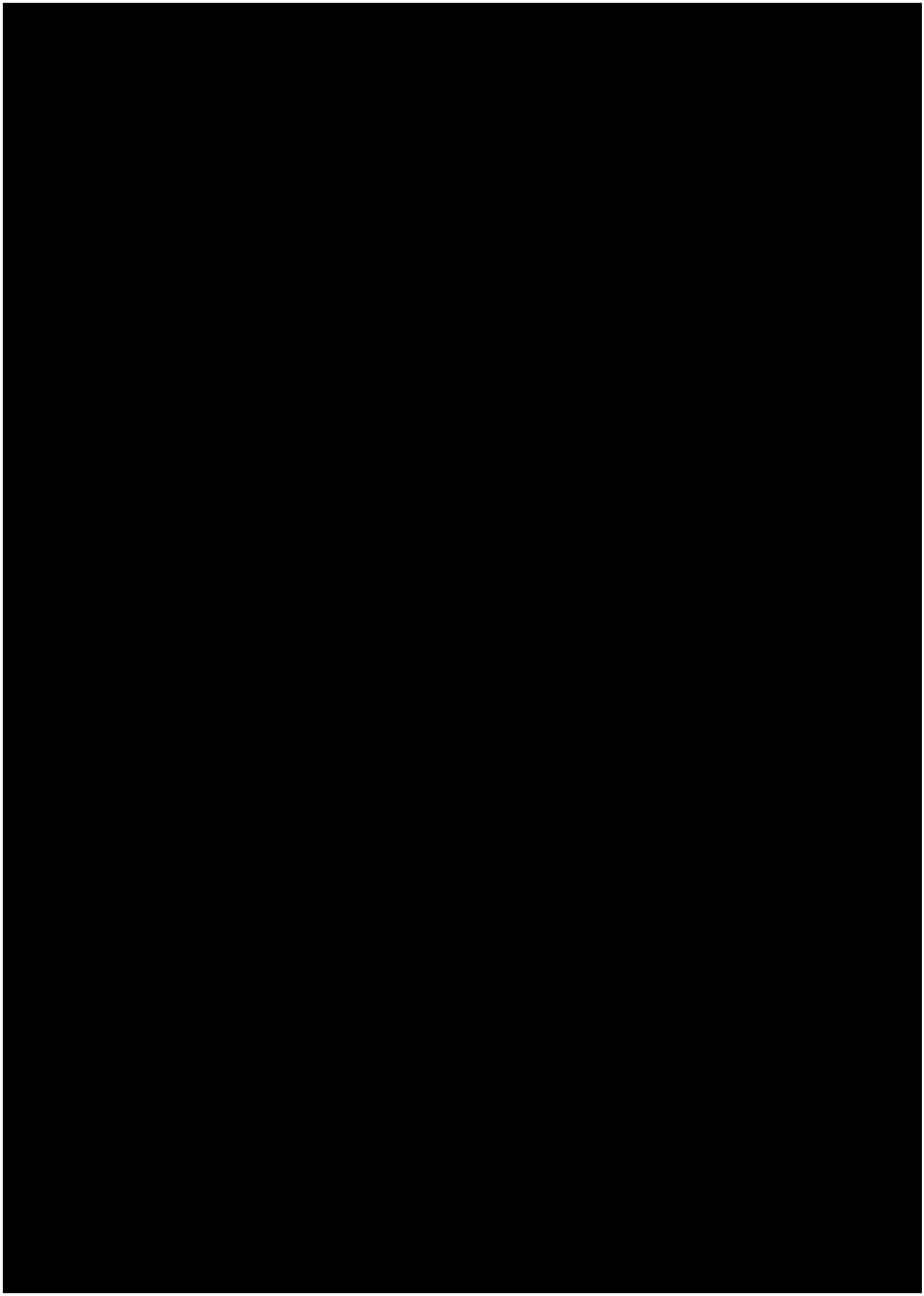


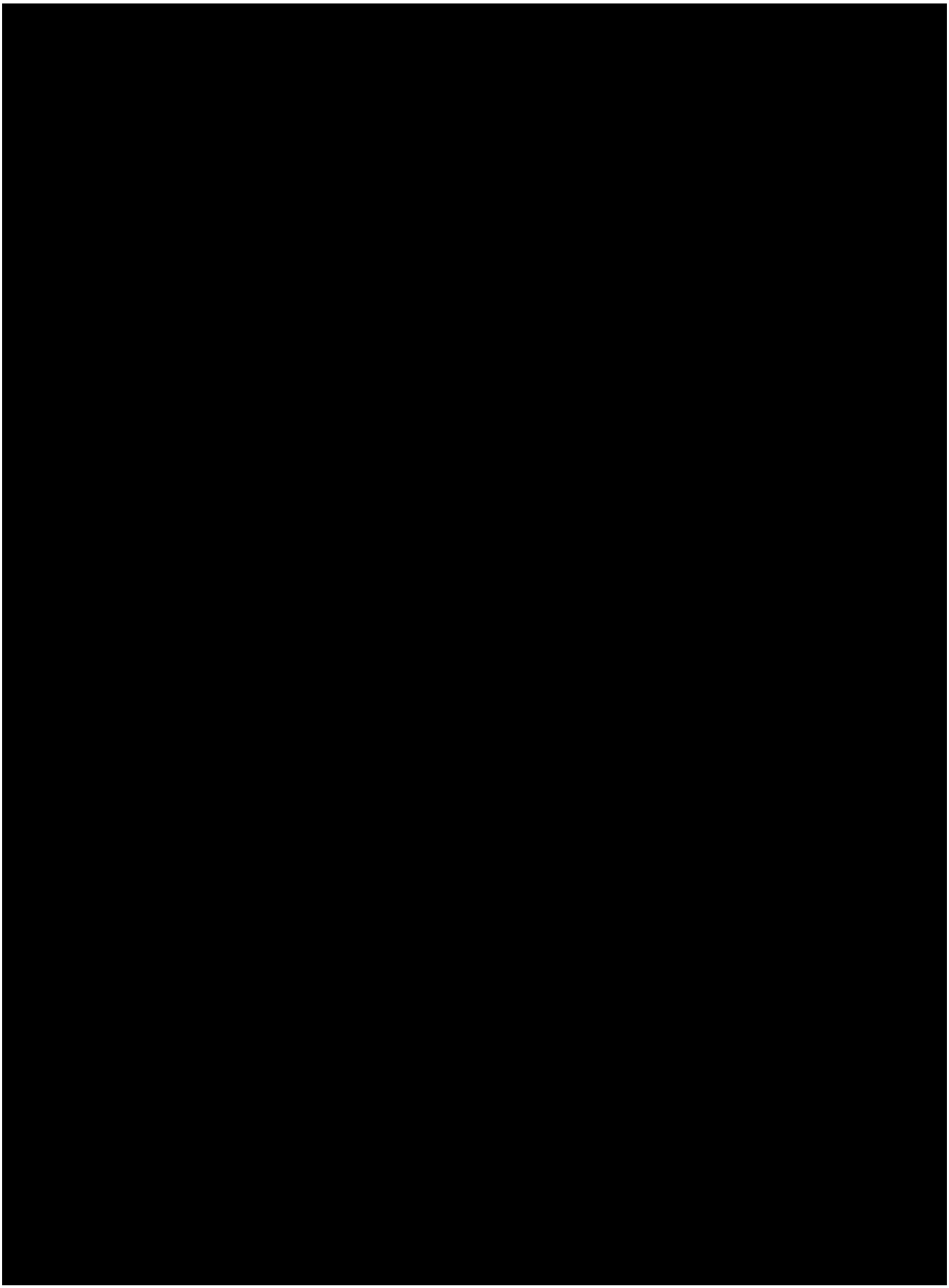


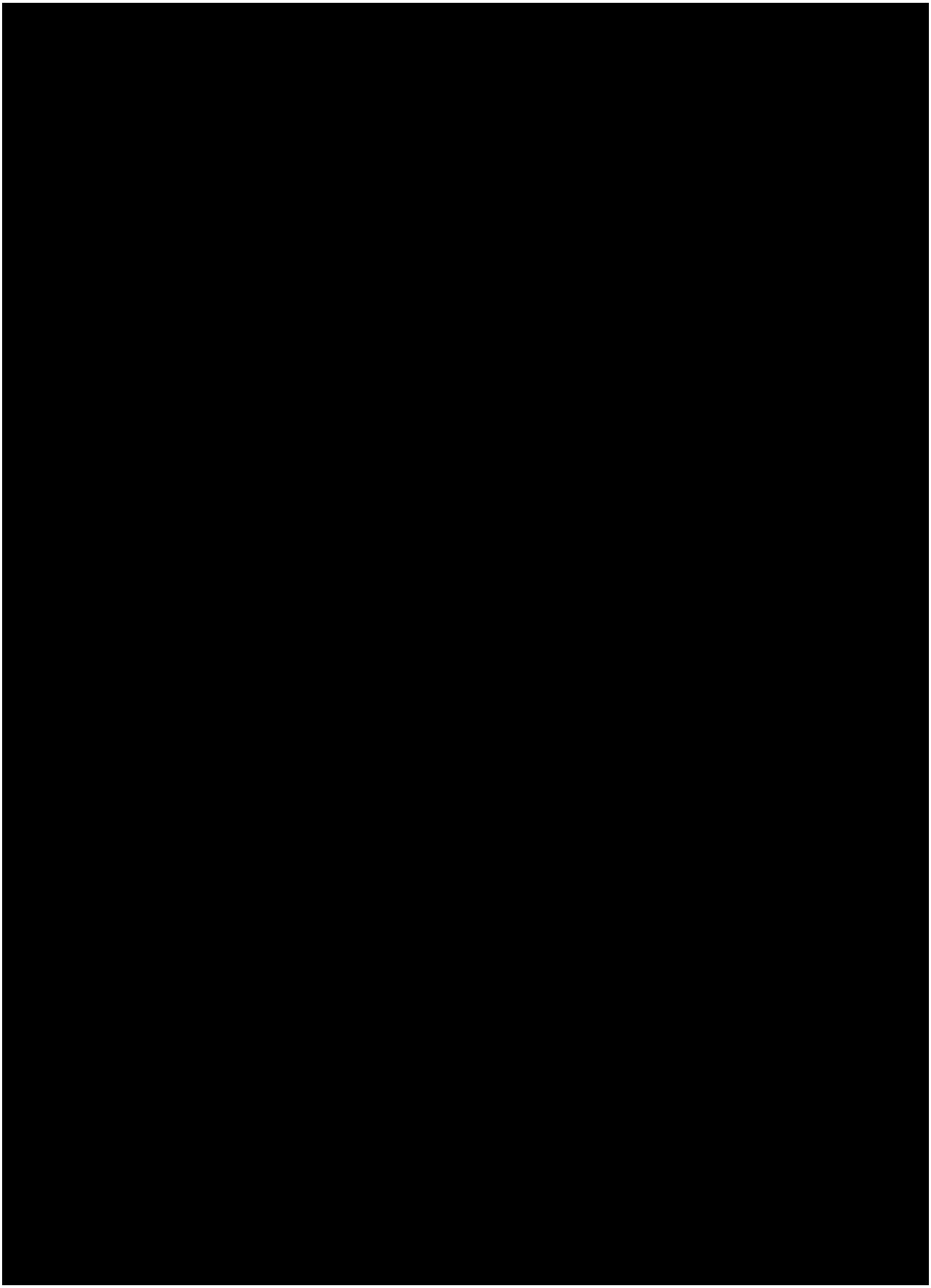












APPENDIX
352-368

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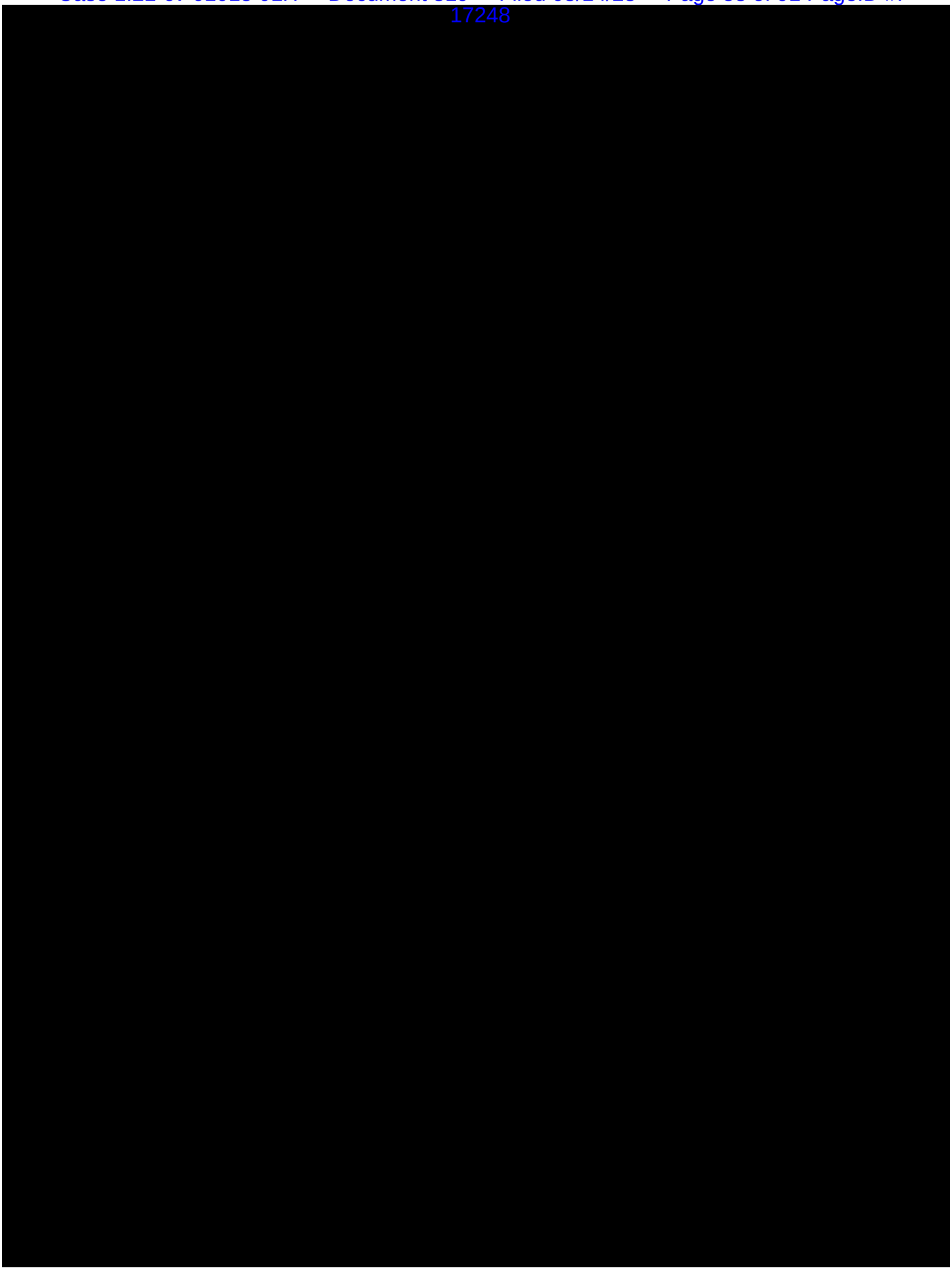

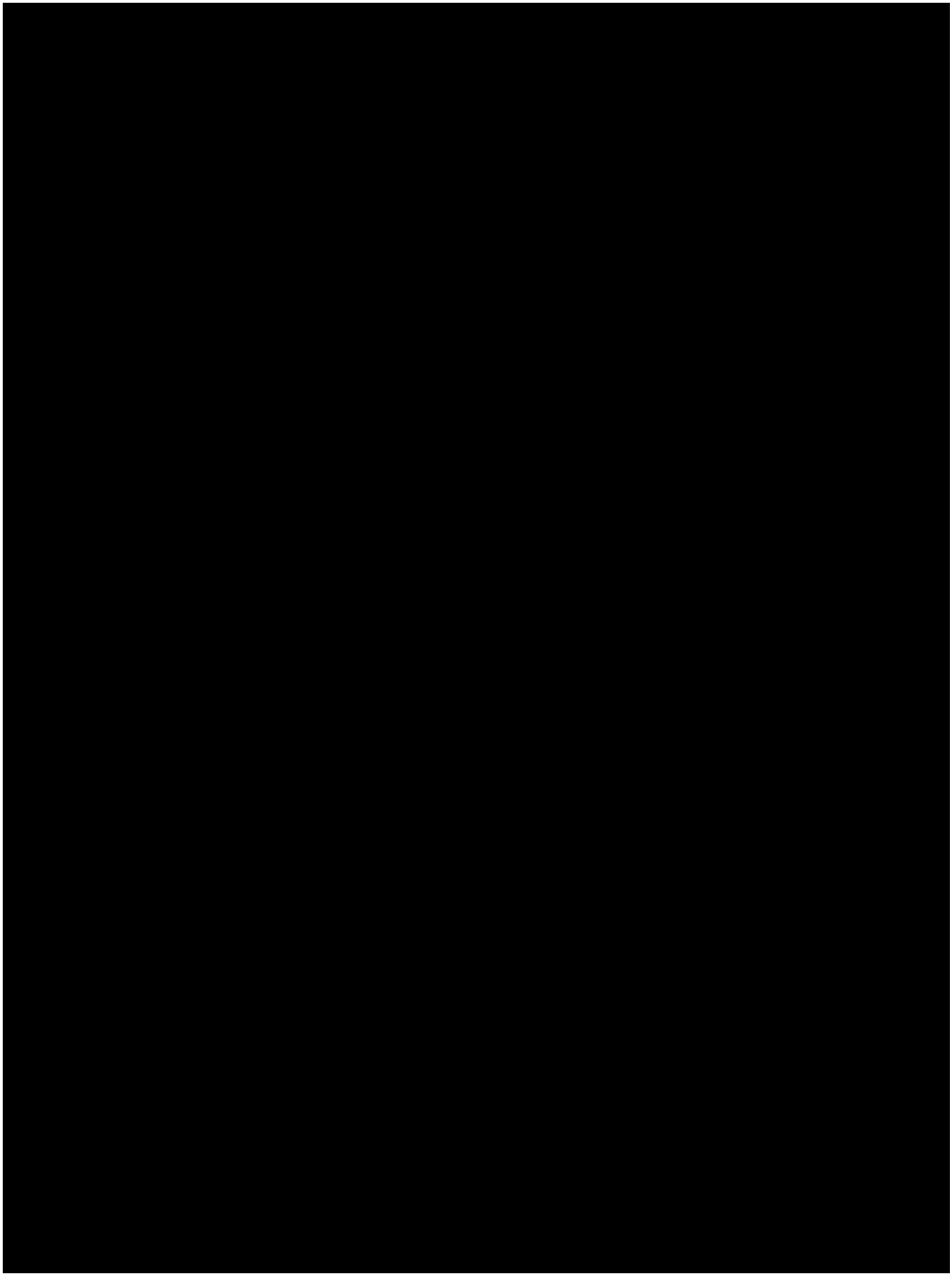

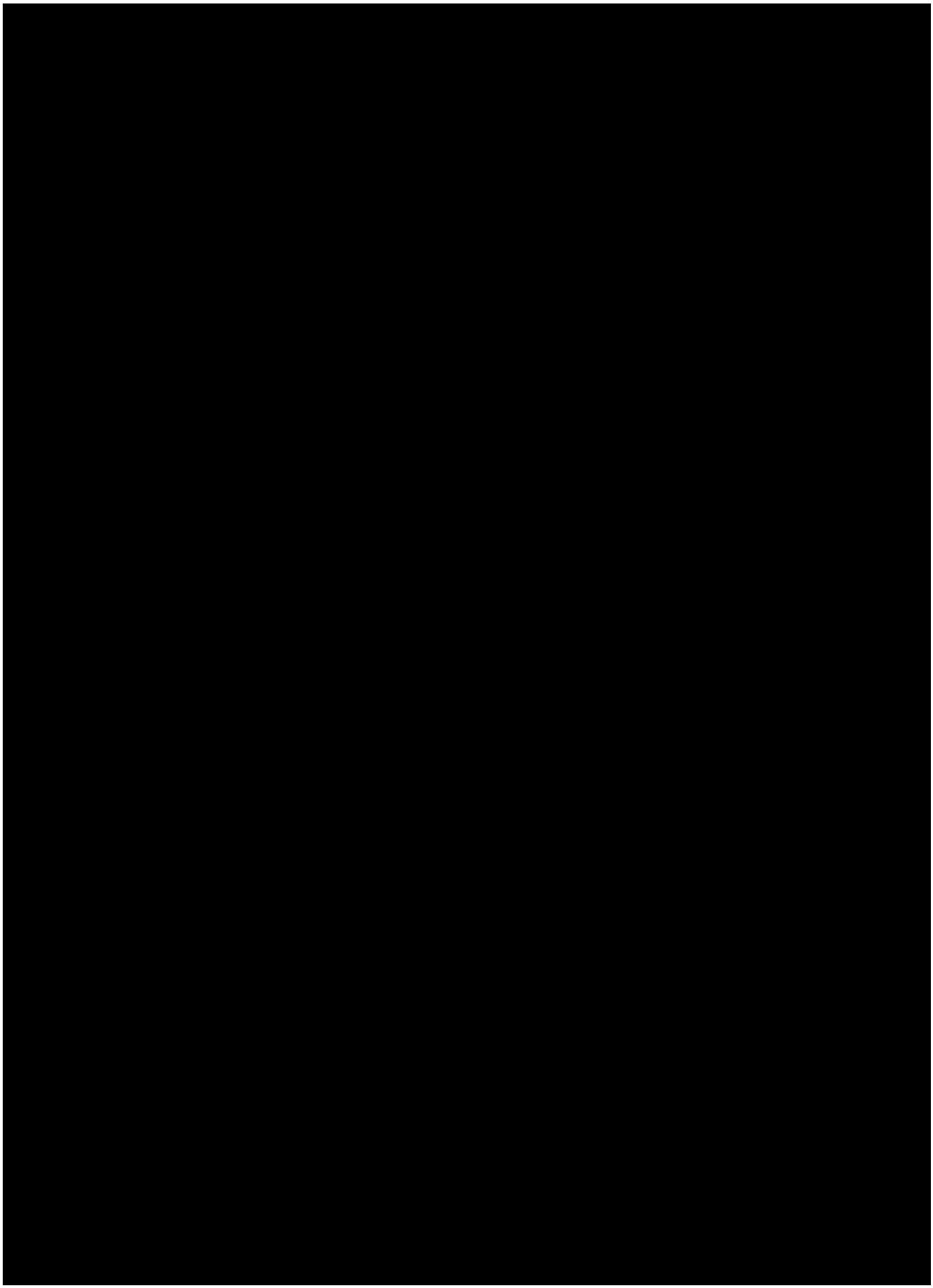

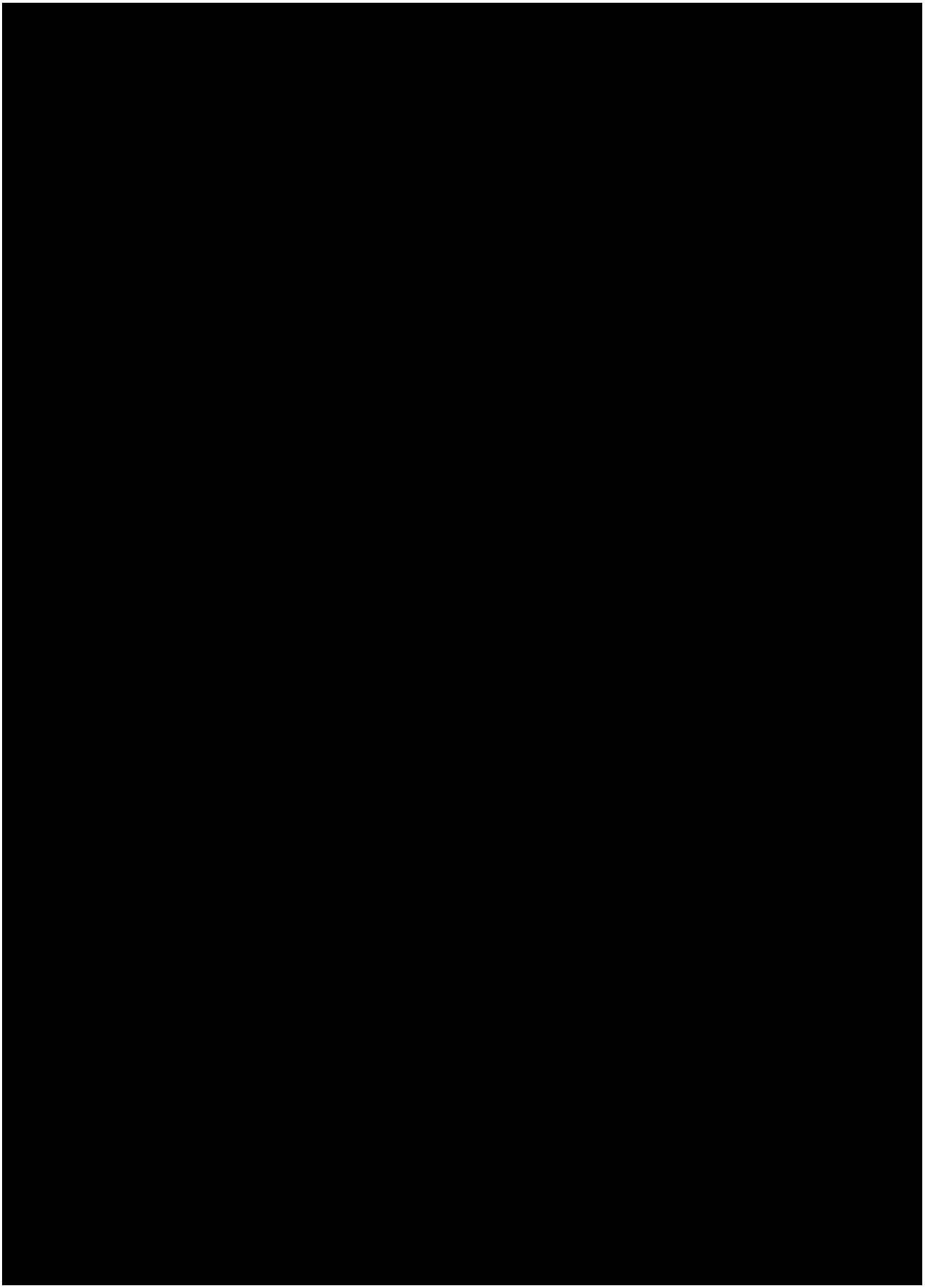

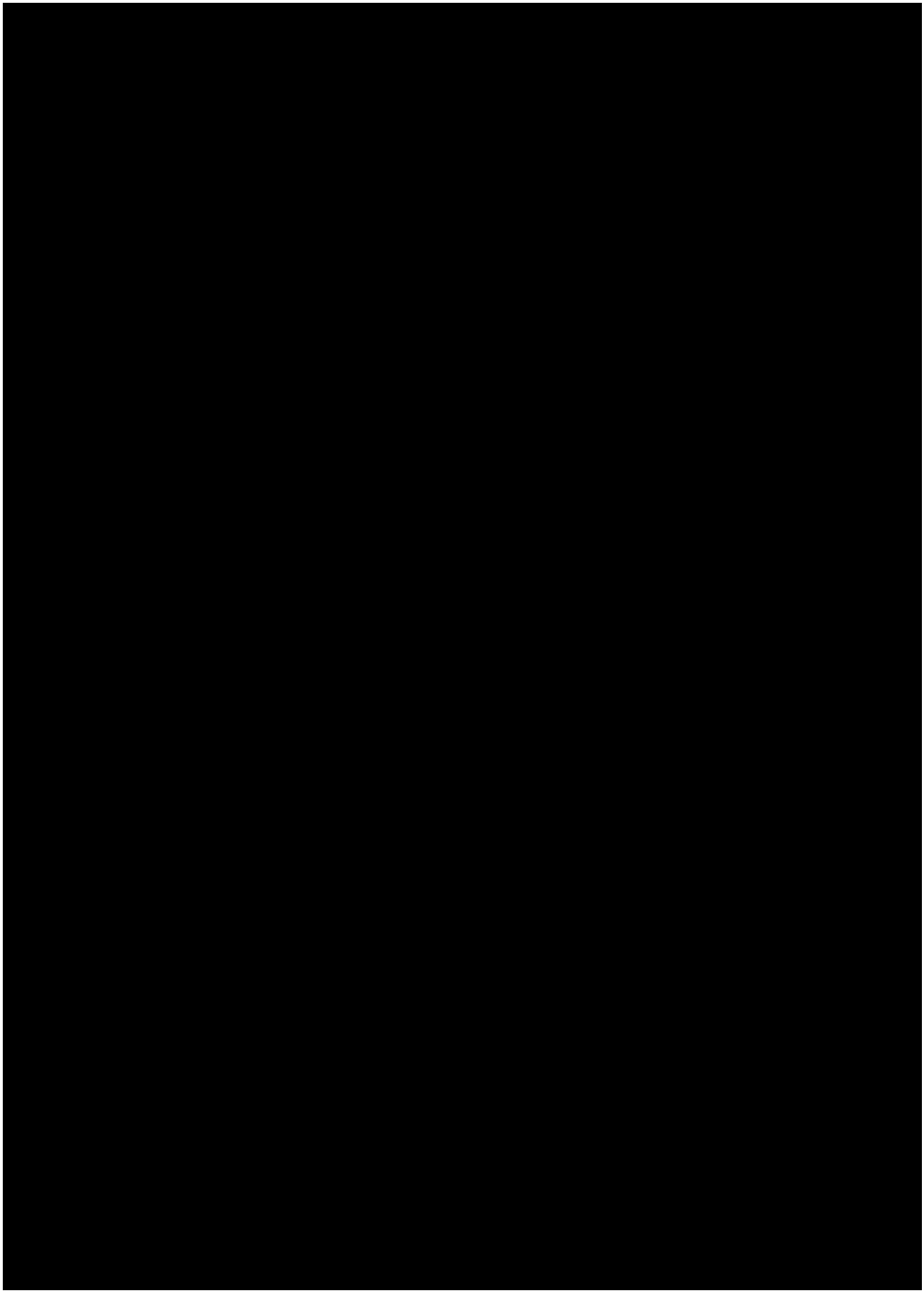

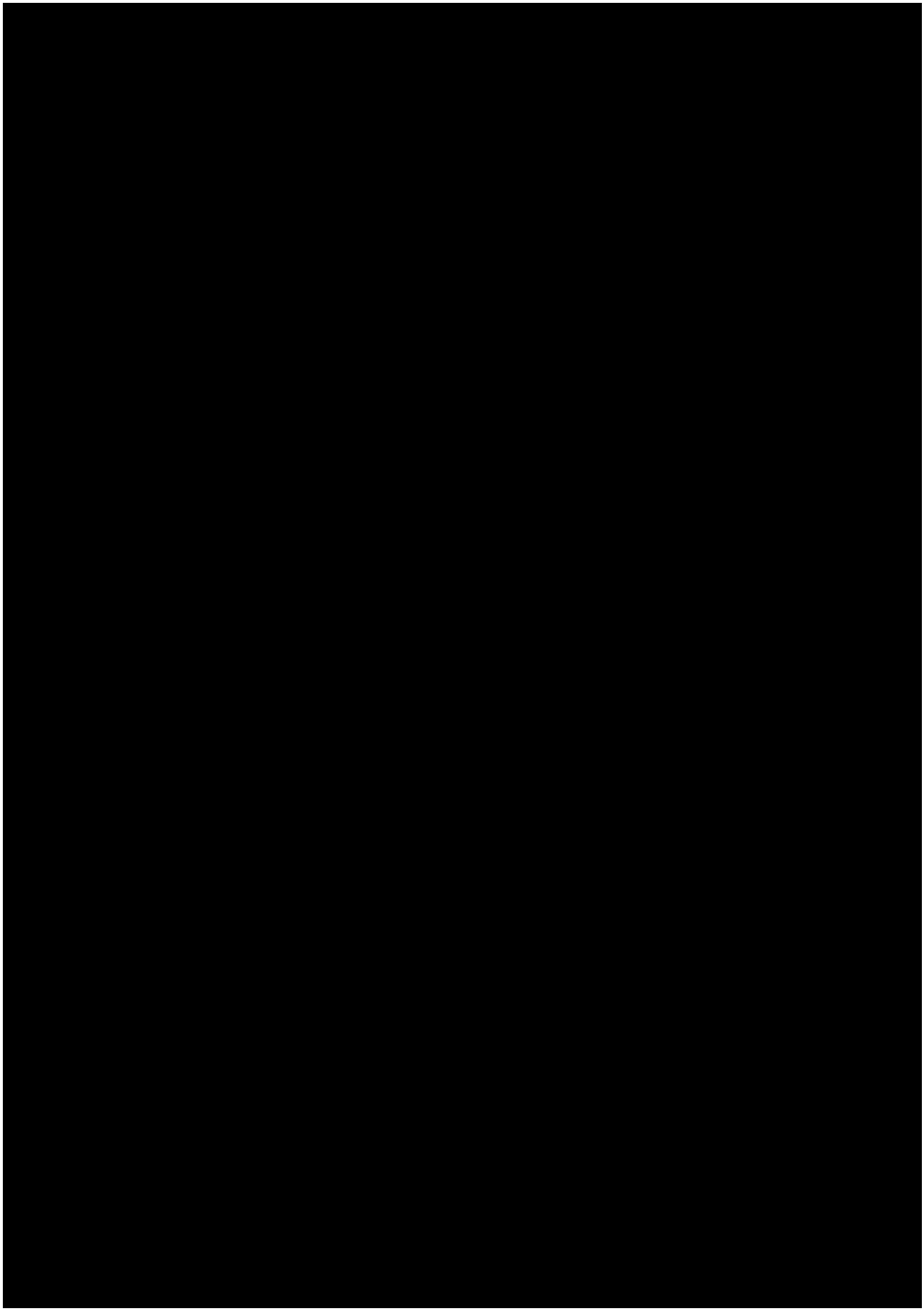

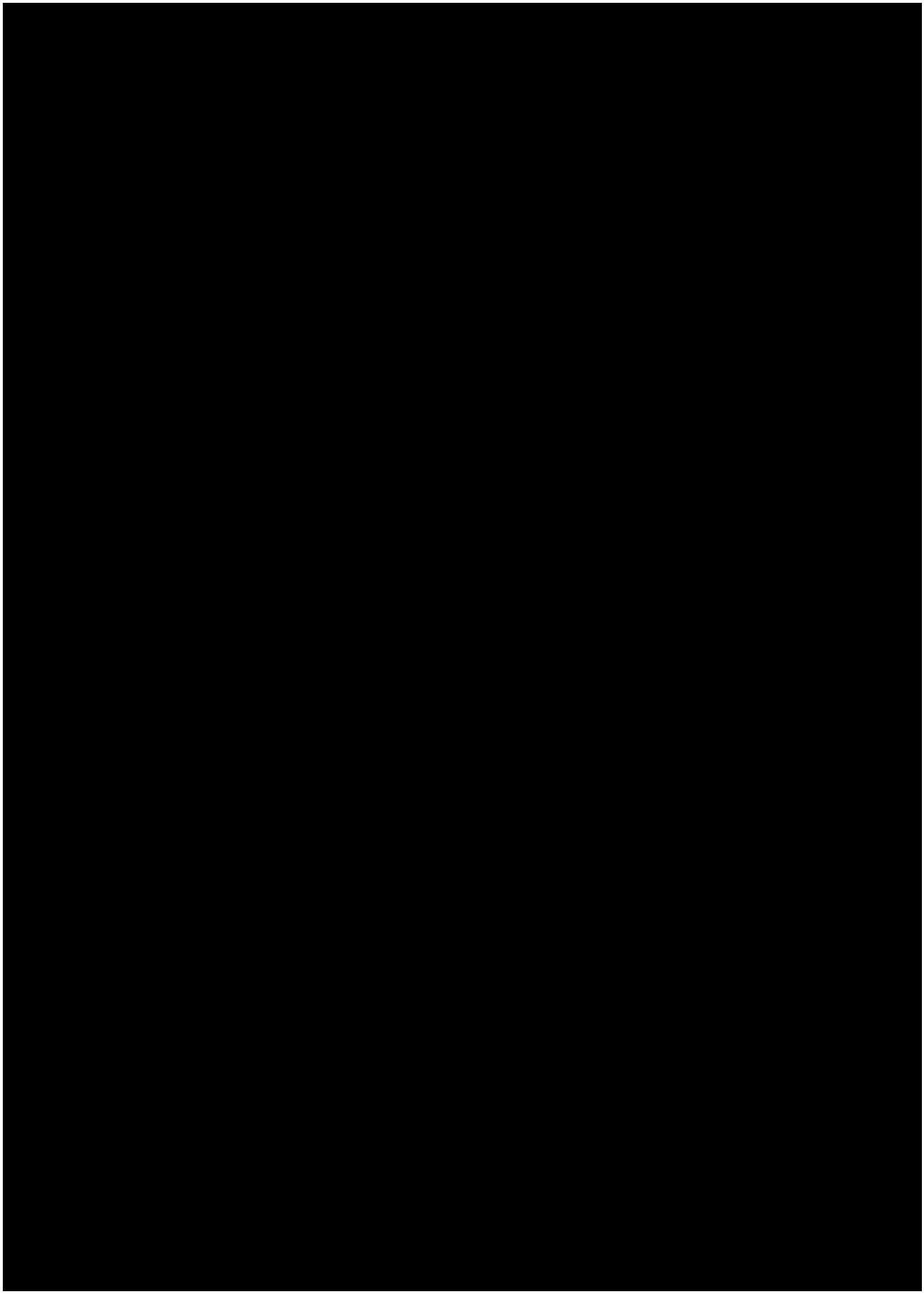

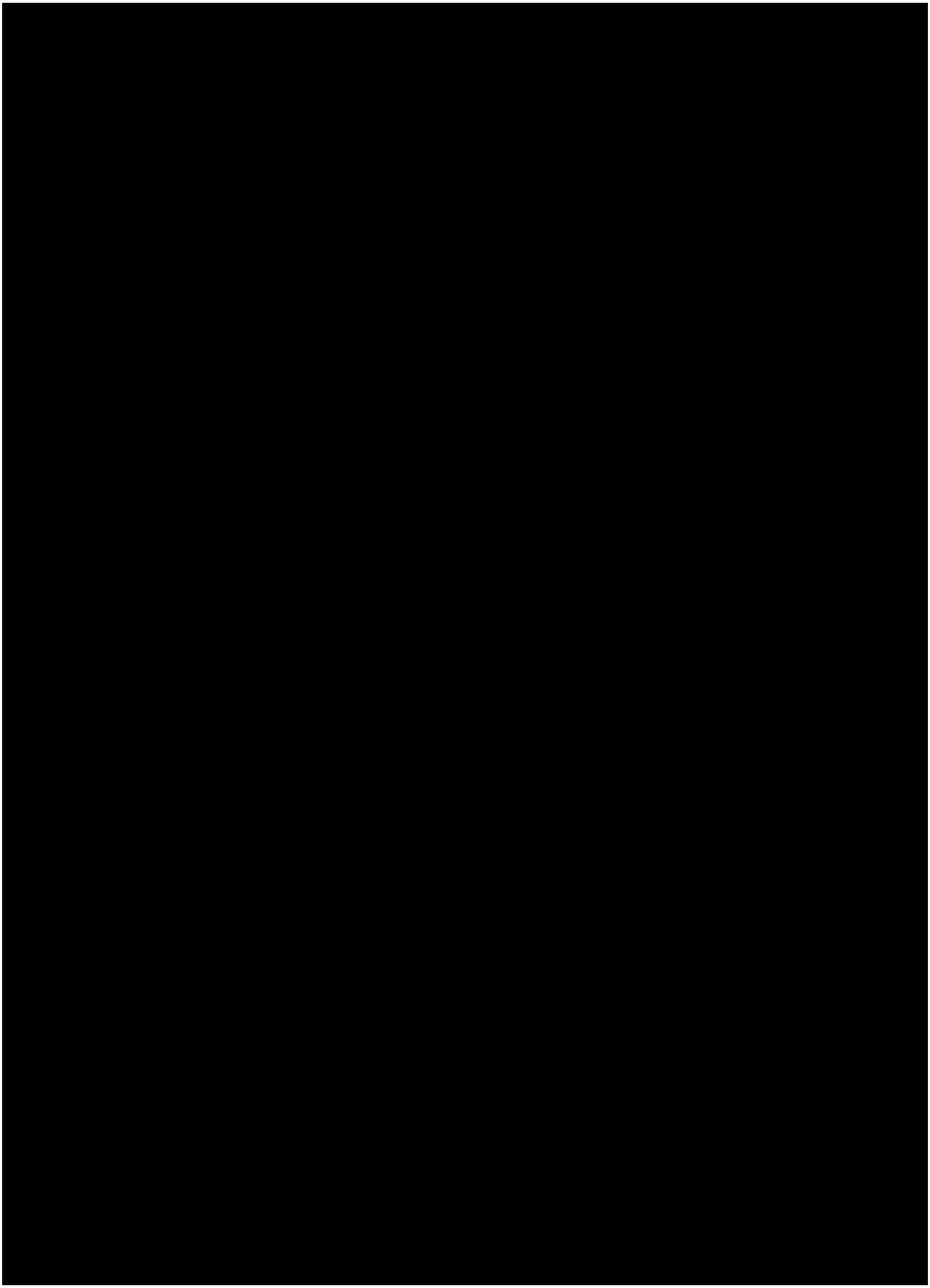

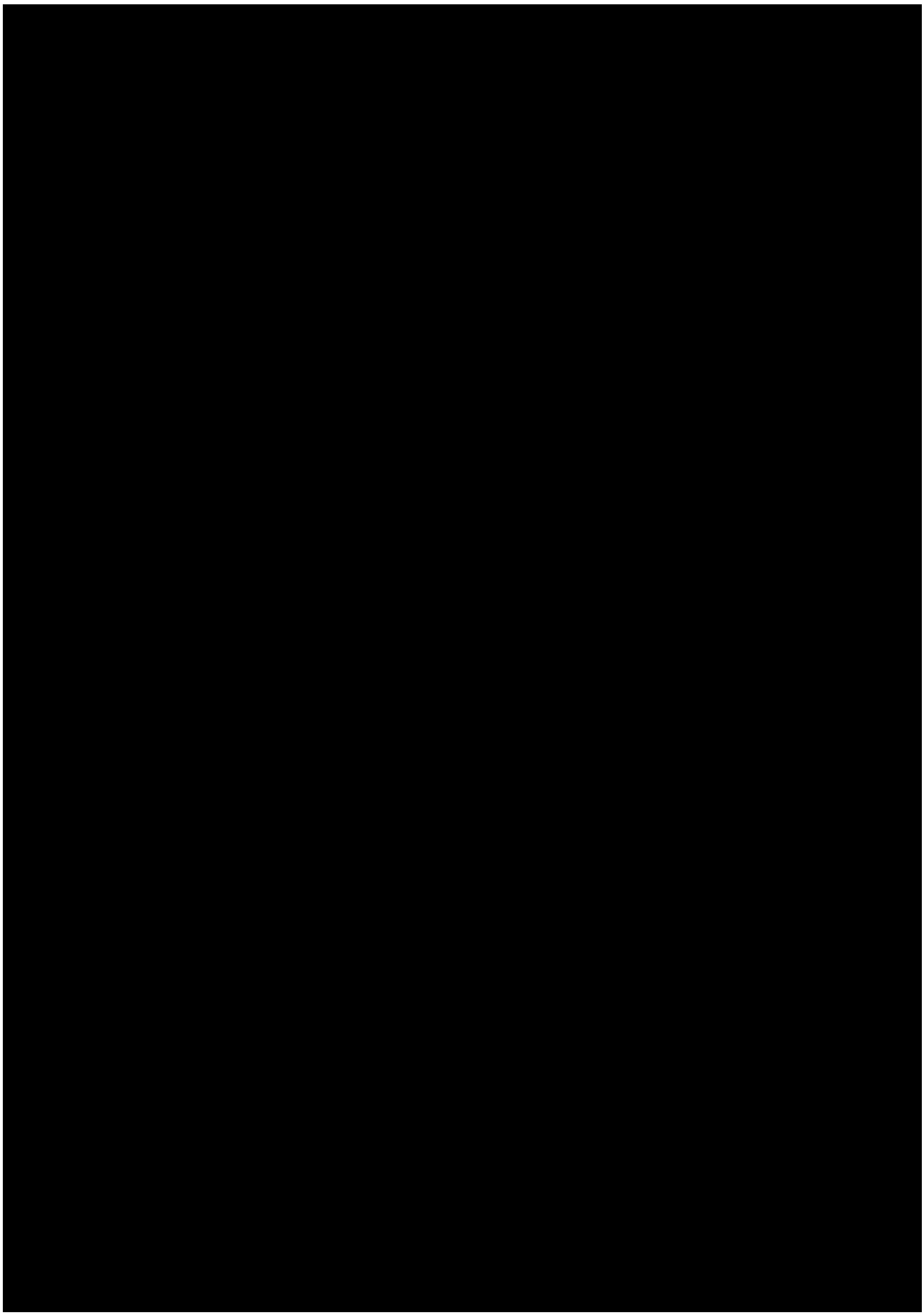

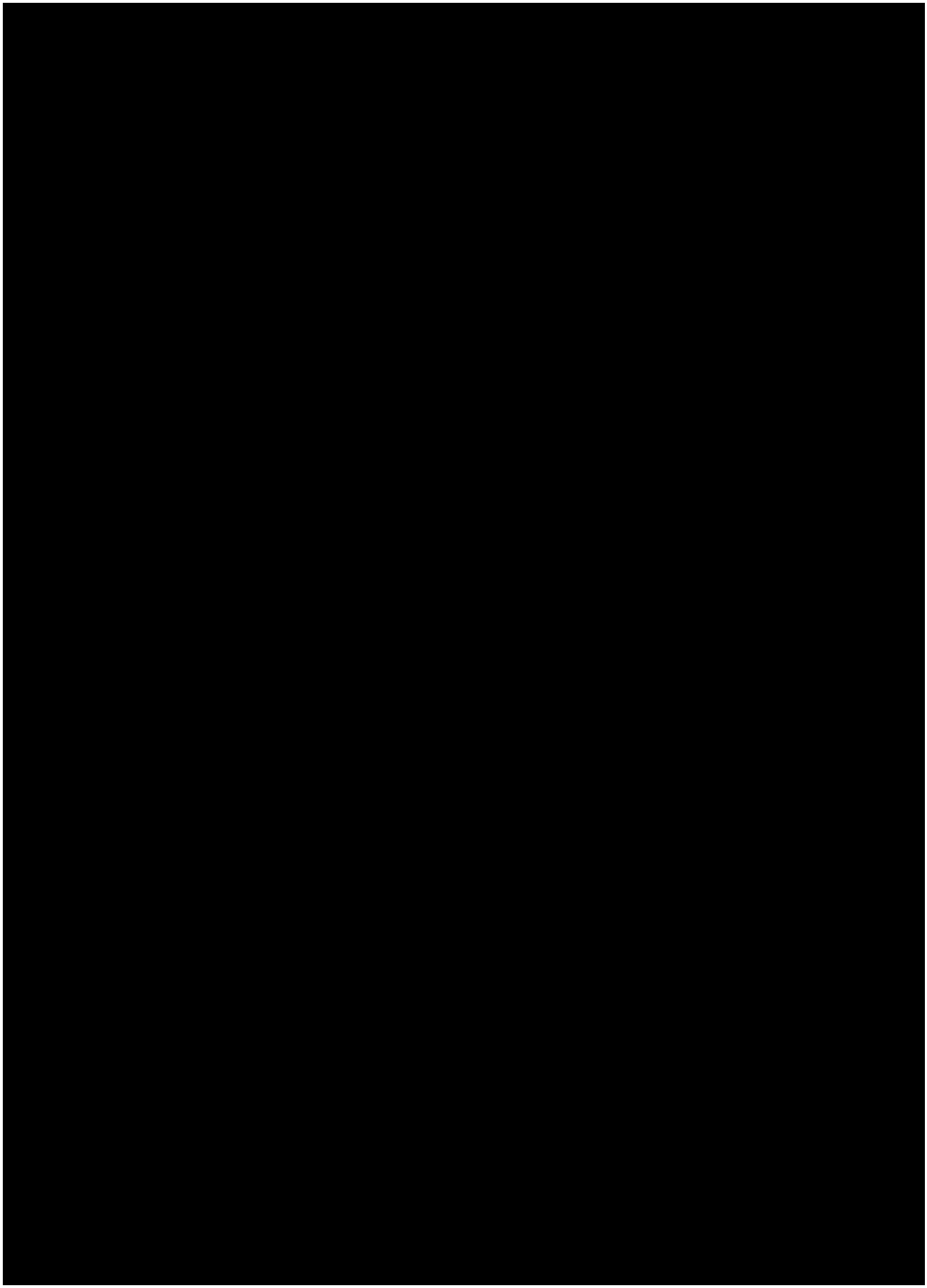

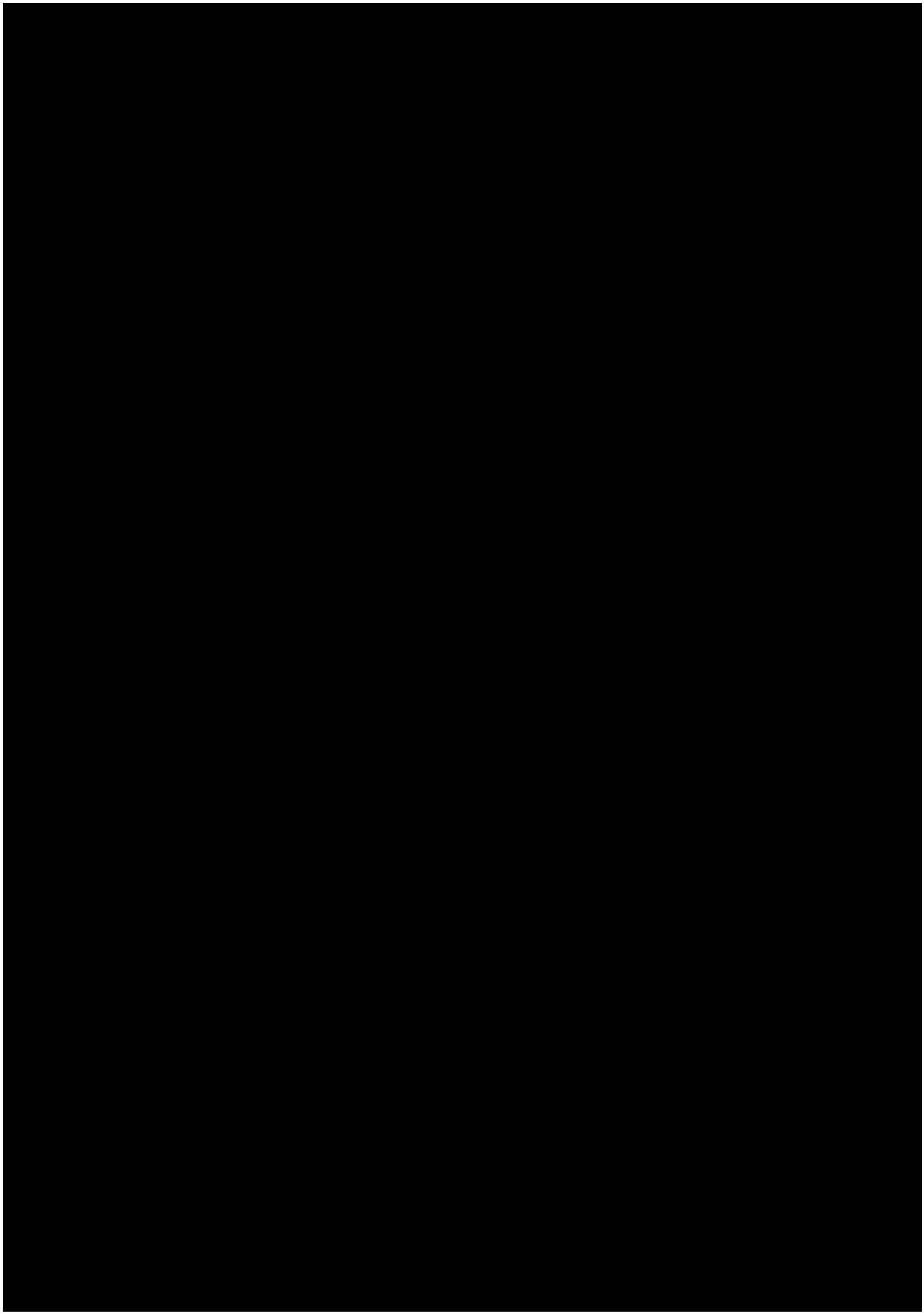

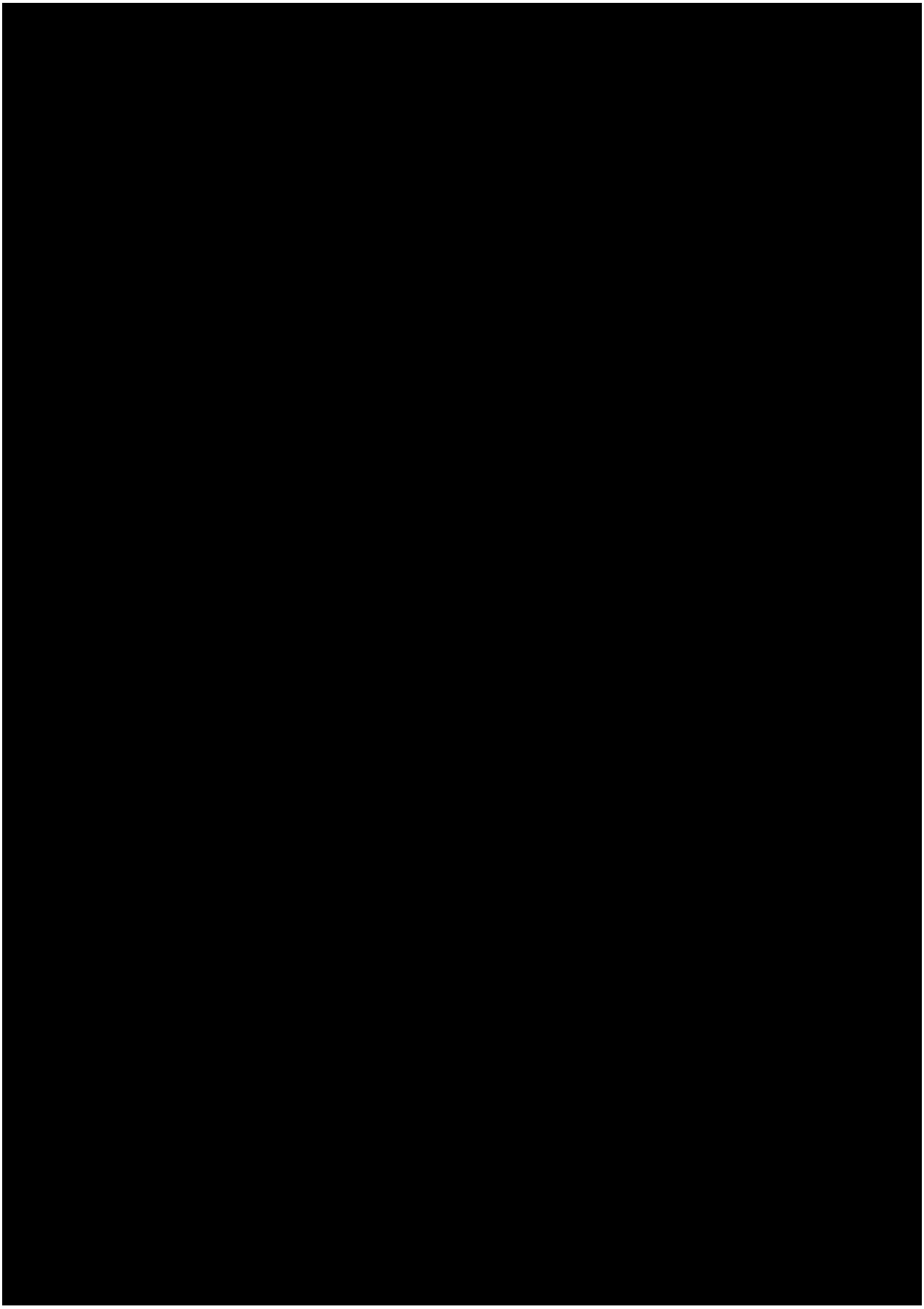

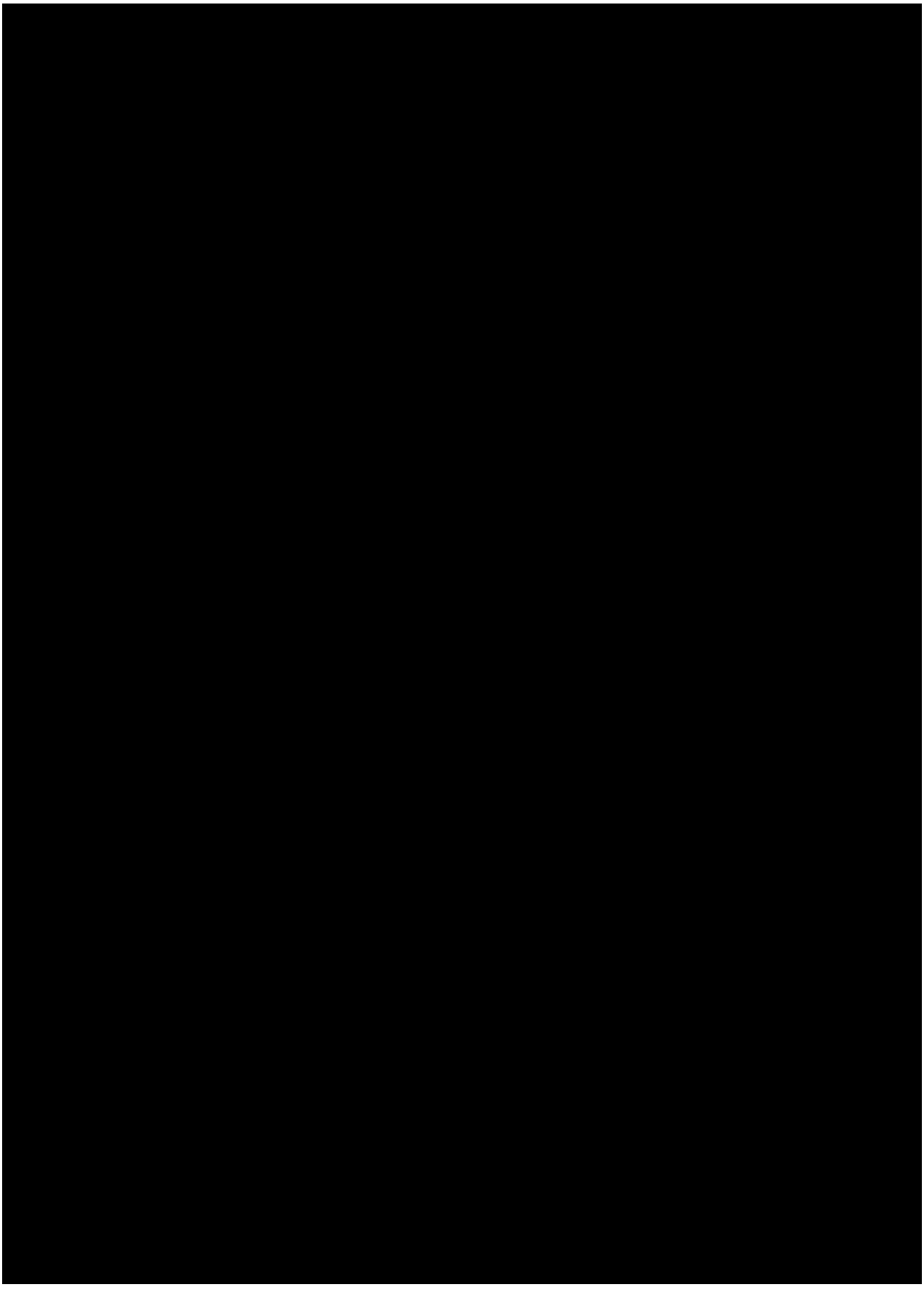

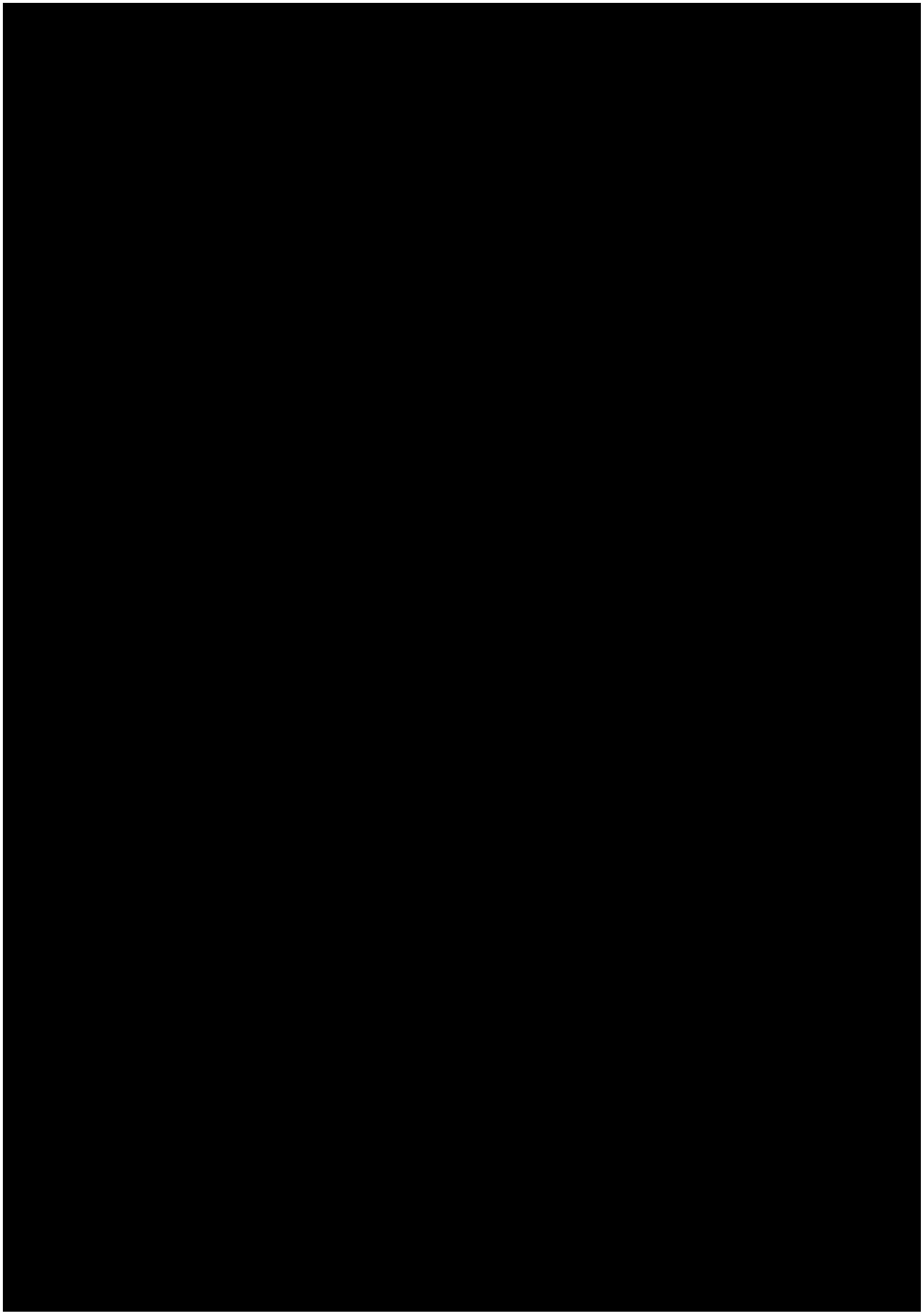

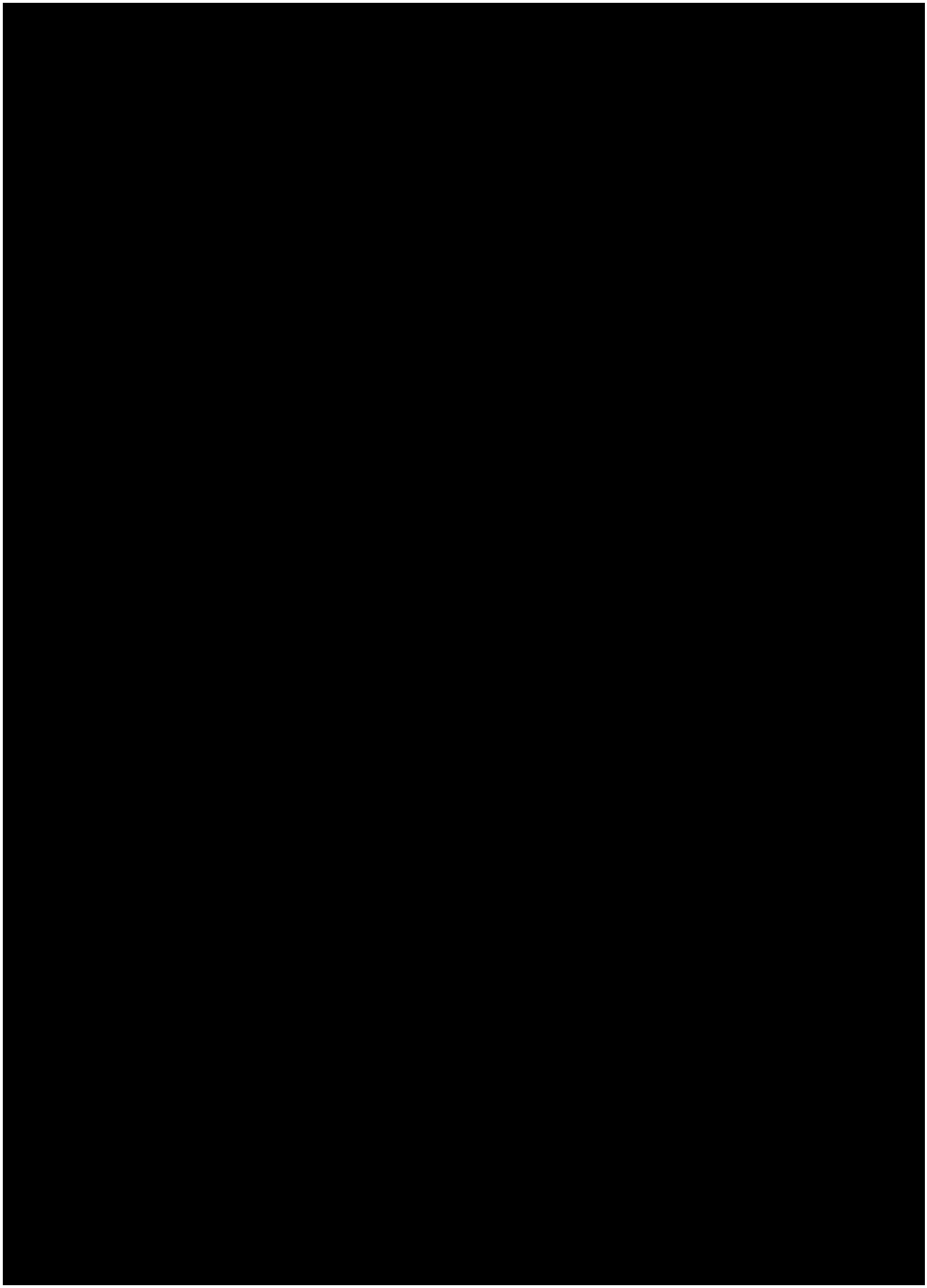

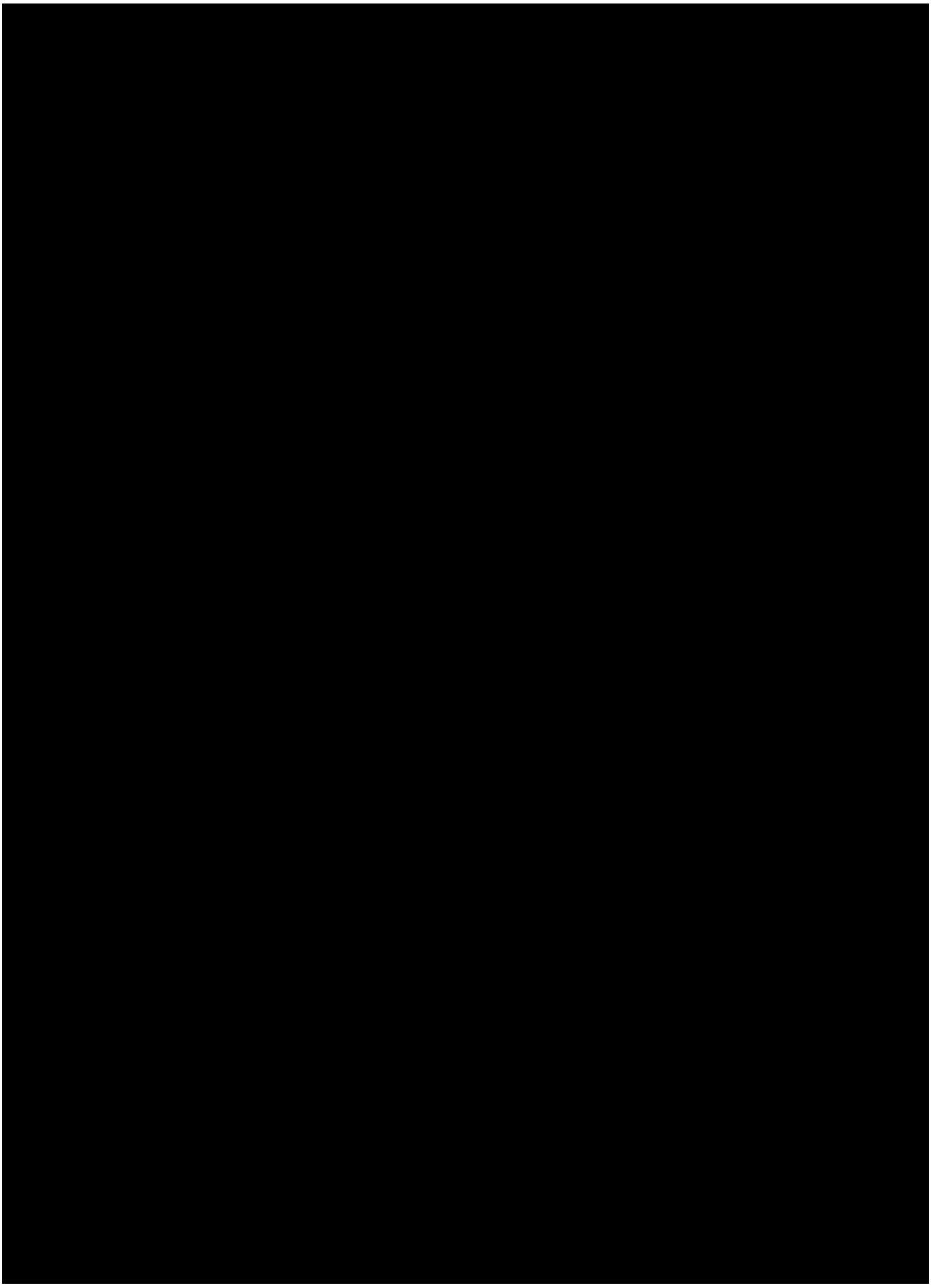

APPENDIX
369-378

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD., Plaintiff, v. SAREPTA THERAPEUTICS, INC., Defendant.	)	C.A. No. 21-1015 (GBW) [redacted]
SAREPTA THERAPEUTICS, INC. and UNIVERSITY OF WESTERN AUSTRALIA, Defendant/Counter-Plaintiff, v. NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC. Plaintiff/Counter-Defendants.	)	

SAREPTA THERAPEUTICS, INC. AND THE UNIVERSITY OF WESTERN AUSTRALIA'S ANSWERING LETTER BRIEF IN OPPOSITION TO NIPPON SHINYAKU'S MOTIONS TO COMPEL

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June 19, 2023

Dear Special Master Squire:

Sarepta Therapeutics, Inc. ("Sarepta") and the University of Western Australia ("UWA") write in opposition to Nippon Shinyaku Co., Ltd. ("NS")'s two motions to compel. With respect to Dispute #1, NS's fishing expedition for virtually any Sarepta license appears to be part of a concerted multi-judge, multi-district effort to improperly extract sensitive commercial information from a direct competitor. The scope of licenses that NS seeks—irrelevant to the claims and defenses of this action—goes far beyond the proportionality standard that Rule 26 requires and far beyond NS's prior requests. With respect to Dispute #3, NS has not met its burden to compel Sarepta and UWA to produce at least one of Dr. Sue Fletcher and Dr. Graham McClorey for deposition. As explained below, Drs. Fletcher and McClorey are not under Sarepta or UWA's control, are not obligated to testify under the terms of their assignment agreements, and do not possess necessary, relevant information proportional to the needs of this case. Both of NS's motions to compel should be denied.

I. NS'S DEMAND FOR ALL DMD AND AON LICENSES IS NOT PROPORTIONAL TO THE NEEDS OF THE CASE

Dispute #1 relates to damages. The framework for calculating a "reasonable royalty" pursuant to 35 U.S.C. § 284 was set forth in *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970), and presents a factor test for the factfinder's use. Among those factors are "[t]he royalties received by the patentee for the licensing of the patent in suit…" and "[t]he rates paid by the licensee for the use of other patents comparable to the patent in suit." *Id.* at 1120. Accordingly, Sarepta has produced licenses relevant to the legal and scientific issues of this case. NS has brought this dispute because it seeks sensitive business information from its chief competitor involving different patents and products. The Special Master should not reward NS's disproportionate overreach.

Here, the patents-in-suit relate to a specific class of therapies for treating Duchenne muscular dystrophy, a fatal disease stemming from particular mutations in the dystrophin gene. The therapies at issue here are known as "exon skipping" therapies because they direct the body's protein-translating machinery to "skip" a portion of the genetic sequence to correct for the genetic mutation and produce a truncated but still-functional version of the protein at issue, a structural muscle protein known as dystrophin. All of the patents-in-suit relate to exon-skipping therapies targeting a specific exon in the dystrophin gene: exon 53. The accused products also target exon 53. Just as fact depositions get underway in this matter, NS has dramatically shifted the scope of its discovery demands—now seeking discovery on (1) ***all*** agreements and licenses relating to ***all*** DMD therapies, regardless of whether or not they target exon 53 and regardless of whether they are exon-skipping therapies. Indeed, NS's letter brief and proposed order apparently further seek (2) ***all*** of Sarepta's licenses relating to nucleic acid-based therapies known as "antisense oligonucleotides" (AONs) regardless of whether they skip exons or treat DMD. (*See* NS Br. at 3 (seeking "Sarepta's licenses relating to [antisense oligonucleotides] (the technology at issue) ***and/or*** Sarepta's other DMD products (the disease to be treated by the accused products).").[1] This new AON request was never even raised as part of the parties' dispute (*see* Ex. I) and demonstrates the unreasonable overbreadth of NS's demands.

[1] All emphases added unless stated otherwise.

NS is correct that Sarepta "has not moved" on its position that agreements and licenses for any and all "DMD therapies" are irrelevant and disproportionate to the needs of this case. (NS Br. at 2 n.3) NS's position, in contrast, has substantially expanded. Sarepta has remained consistent in its position since it served its objections in April 2022 to NS's RFP Nos. 101 ("royalty rates paid in the field" for DMD or AON tech) and 149 (all documents related to a December 21, 2019 License, Collaboration, and Option Agreement between Sarepta and pharmaceutical company Roche relating to ex-US rights to a large range of compounds, many irrelevant to this case). Sarepta limited the scope of RFP No. 101 to the accused product, Vyondys 53, and refused to re-produce the Roche agreement, which had been published in redacted form as part of a Sarepta Form 10-K filing. *See* NS Br. Ex. A. Six months later, NS's counsel confirmed in letter correspondence that the scope of this dispute was "[a]ll agreements/licenses ***related to developing exon-skipping oligonucleotides and/or Vyondys53®*** (including Sarepta's agreements with UWA, Biomarin, Roche and Royal Holloway), and any related consulting agreements (e.g., with the UWA inventors)." Ex. J at 2. Sarepta has since produced ***each*** of those enumerated agreements to NS, and NS has had them for months. The parties reached an impasse by early April on redactions to the Roche agreement. Ex. K at 2.

Out of the blue, on May 15, 2023, counsel for NS indicated for the first time that they believed the impasse extended to a far broader scope of documents: "[l]icense agreements relating to DMD therapies ***beyond*** solely exon-skipping therapies (e.g., Sarepta's licenses for SRP-9001, including an unredacted version of the Roche Agreement)." Ex. I at 3. SRP-9001 is a ***gene therapy treatment, not an exon-skipping treatment***, was developed independently of the patents-in-suit, and as of the date of this filing has not been approved by the FDA. Counsel for Sarepta explained there was no impasse, as this broadened scope had never been discussed. *Id.* at 2. Yet, as discussed above, NS's demands have now gotten even broader. (D.I. 206.)

NS has made no showing that it is entitled to all licenses or agreements Sarepta has ever entered in its decades-long history that tangentially relate to AONs or treatment of DMD. Indeed, NS's letter brief itself frames the scope of this litigation in a way that defeats its own position: "This case involves cross-assertions of patent infringement between NS, on one hand, and Sarepta and UWA, on the other, ***relating to exon-skipping AON products offered for sale in the U.S. for the treatment of DMD***." (NS Br. at 1). NS's conclusory argument to the contrary later in its brief that "[t]he relevancy of Sarepta's DMD products to the exon-skipping market cannot be reasonably disputed" (*Id.* at 3) falls flat. For example, notwithstanding NS's arguments, documents and testimony from the June 14th deposition of Sarepta 30(b)(6) witness [redacted] are not contradictory, despite NS's attempt to reframe that testimony with selective, out-of-context quotes.[2] [redacted]

[2] Sarepta notes for the record that the rough draft deposition transcript NS cites in its opening letter brief and included as NS Ex. D states that "[t]he uncertified rough draft transcript cannot be quoted in any pleading or for any other purpose and may not be filed with any court or other tribunal." Sarepta cites it here only as a matter of fairness, and does not agree that any such citation by NS was proper.

NS's assurances to the Special Master that they "do[] **not** broadly seek all of Sarepta's licensing agreements" (emphasis in original) ring hollow when Sarepta's only FDA-approved products now and in the immediate future are AON or DMD therapies. And NS's declaration that the discovery sought is "proportional" because it "has not withheld like-in-kind documents" misses the mark on two fronts. First, the parties' non-exon-skipping products are not comparable. NS's cell therapy, partnered with Capricor, is still enrolling patients for clinical trials and could be years away from approval, if any. In contrast, Sarepta's SRP-9001 product has advanced further through the process and currently has a regulatory action date of June 22, 2023. The number of associated agreements is simply higher for the more mature product. And second, NS only produced the Capricor agreement in the last two weeks. The "inquiry" by Sarepta's counsel came about after NS's counsel asserted on multiple occasions that NS had already produced all of its DMD licenses, an assertion disproven by a few minutes of internet searching. Ex. L at 1-3. Sarepta never actually sought the agreement or asserted that it was relevant to this matter. To the contrary, Sarepta's counsel noted that, like the agreements sought by NS, the NS/Capricor agreement was not relevant to this case. *Id.* at 2-3. NS should reap no benefit for unilaterally producing a single non-relevant agreement four months after the deadline for substantial completion in a transparent attempt to manufacture an inequity that does not exist.

The standards for relevance and proportionality in this district are set forth in the caselaw, none of which NS cites. As the party seeking discovery, NS "bears the burden of demonstrating the relevance of the sought information to either the claims, defenses, or the subject matter of the litigation." *Inventio AG v, ThyssenKrupp Elevator Am. Corp.*, 662 F. Supp. 2d 375, 381 (D. Del. 2009). NS has not carried that burden with respect to ***all*** AON and DMD licenses. NS's position appears to be that there ***might*** be something useful in these irrelevant documents, so it should get free rein to review them. But that is not the standard: NS must prove, especially this late in fact discovery, that "its request is premised on more than 'mere suspicion or speculation.'" *Tessera, Inc. v. Broadcom Corp.*, 2017 WL 4876215, at *5 (D. Del. Oct. 24, 2017) (citation omitted). Sarepta has produced its relevant exon-skipping licenses and agreements to NS, commensurate with the scope of the claims and defenses in this case ***and*** the parties' prior negotiations. NS's belated demand to cast the net further should yield under Fed. R. Civ. P. 26(b) to the burden and risk of harm to Sarepta.

II. NS IS ENTITLED TO NO FURTHER UNREDACTION OF THE ROCHE AGREEMENT

Even if Dispute #1 is properly cabined to the Roche agreement, NS fares no better. NS's selective, misleading quotation of what Sarepta's counsel allegedly "confirmed" in a March 20, 2023 email demonstrates the weakness of its position. NS Br. at 3. The actual sentence from Sarepta's counsel's email reads "It should be clear upon review of that document that Roche was granted [redacted] in territories ***outside the relevant US market***." NS Br. Ex. B at 8. With respect to the relevant technologies in this case, the Roche agreement is not a license; it is [redacted]. When the facts regarding the Roche agreement are correctly laid out, NS's arguments fall apart. Morgan Lewis's co-counsel stated the matter succinctly during a discovery dispute hearing just last month regarding the Roche agreement

before Judge Andrews in a different case, *REGENXBIO Inc. v. Sarepta Therapeutics Inc.*, No. 20-1226-RGA (D. Del.). In that case, which deals with the same SRP-9001 gene therapy for which NS now seeks discovery in this case, counsel stated that "the portions of the agreement that relate to ***exon skipping*** and gene editing….are parts of the agreements that…we're not interested in." Ex. M at 10:14-20. The reason? "[T]hey're not particularly relevant." *Id.* at 10:22. It is notable that one court in this district is being told exon skipping portions of the Roche agreement aren't relevant to gene therapy while another is now being told the opposite.

NS's insistence that it must see the Roche agreement in "unredacted" form is audacious given its counsel's parallel involvement in the *REGENXBIO* case, where redactions to "irrelevant" sections of the agreement were maintained throughout the document even after Court involvement. *See* Ex. M at 34:20-24 (Judge Andrews permitting redaction of "exon skipping" portions of the Roche agreement because "everyone agrees those dollars are just irrelevant.") As discussed above, Morgan Lewis's apparent refusal to use different counsel for these different matters against the same party (Sarepta) creates a real and unnecessary danger that these common counsel will be unable to cabin differently-redacted versions of the same document(s) across the different matters involving different subject matter.

The Roche agreement is a broad collaboration agreement that covers ex-US rights to different therapies and different technologies than those at issue in this case. To the extent NS believes it is entitled to unredaction because the Roche agreement demonstrates "rates paid by the licensee" for purposes of a reasonable royalty analysis, the facts say otherwise: [redacted]. Sarepta respectfully requests that NS's motion to compel be further denied to the extent it seeks "unredaction" of the Roche agreement's sensitive terms.[3]

III. SAREPTA AND UWA CANNOT COMPEL DRS. FLETCHER AND MCCLOREY TO APPEAR FOR DEPOSITION

The threshold question in Dispute #3 is whether or not Sarepta or UWA have control over Drs. Fletcher and McClorey such that they can compel them to appear for deposition. The facts and caselaw establish that they do not. Drs. Fletcher and McClorey (residents of Australia and the U.K., respectively) are not current employees of either Sarepta or UWA. Nor do they have contractual obligations to testify. The assignment agreement they executed transferring their patent rights to UWA does not even mention testifying.[4] *See* Ex. E to NS Br. ("UWA Assignment Agreement") at 3. All that the UWA Assignment Agreement contractually obligates the inventors to do is sign documents:

[3] To the extent the Special Master is inclined to grant NS's motion to compel Sarepta's agreements with Roche or any other third party, Sarepta requests an *in camera* review of the documents to facilitate reasonable redactions of sensitive business material.

[4] This stands in sharp contrast to the assignment agreement executed by current NCNP employee Dr. Takeda with NS and NCNP. *See* Sarepta Br., Ex. A at 3.

> ASSIGNORS ***agree to execute all instruments and documents required*** for the making and prosecution of applications for United States and foreign letters patent on said invention, ***for litigation regarding letters patent***, or for the purpose of protecting title to said invention or letters patent therefore.

Id. An obligation to execute documents is not an obligation to testify—and does not support a motion to compel a witness to appear for deposition, as Judge Stark specifically found in *Aerocine AB v. Apieron Inc.*, 267 F.R.D. 105, 109-112 (D. Del. 2010). In *Aerocrine*, Judge Stark denied the defendant's motion to compel the patentee to produce two co-inventors whose assignment agreements, like those of Drs. Fletcher and McClorey, did "not reference providing any testimony in connection with enforcing the [asserted patent] in the U.S." *Id.* at 109. Judge Stark noted that the assignment agreement only obligated the inventors to "execute and deliver . . . documents, forms, and authorizations . . ." and "d[id] not contain particularized language obligating [the inventors] to appear in the United States for a deposition." *Id.* at 110. On this basis, Judge Stark denied the motion to compel and emphasized that the inventors' "agreement ***does not specifically obligate them to testify***." *Id.* (emphasis added). Thus, NS's argument that "[t]his language is akin to those that courts in this District have found to obligate production of foreign inventors" (*see* NS Br. at 7), citing to *Aerocrine*, is simply wrong. Indeed, in making this argument, NS highlights the language "for litigation regarding letters patent" but ignores the beginning of the sentence, which identifies what action the inventors are actually obligated to perform: "execut[ing] all instruments and documents." NS Br. Ex. E at 3.

The only other case NS cites, *Amgen, Inc. v. Ariad Pharms., Inc.*, C.A. No. 06-259-MPT, 2007 WL 1425854 (D. Del. May 14, 2007) (NS Br. at 7), relied on very different assignment agreement language that went well beyond an obligation to sign documents. In *Amgen*, the assignment agreement required the inventors "to ***perform any other lawful acts*** which may be deemed necessary to secure fully the aforesaid invention" and included "***the giving of testimony*** in any interference or other proceeding in which said invention or any application or patent directed thereto may be involved." *Amgen*, 2007 WL 1425854, at *1 (emphasis added). Judge Thynge found this language was sufficient to compel the patentee to produce the inventors for deposition, noting that "[t]he assignment provision means that all inventors have agreed to testify in any legal proceeding involving the invention or patent directed thereto . . . ." *Id.* at *3; *see also Aerocrine*, 267 F.R.D. at 112 (granting a motion to compel for different inventors having a different assignment agreement than that discussed above, stating "in *Amgen*, as here, the inventors' assignment agreements . . . ***specifically obligated the inventors to testify in any legal proceeding regarding their patents***.") (citation omitted, emphasis added).

Here, unlike in *Amgen*, there is no requirement in the UWA Assignment Agreement for the inventors to testify or perform "any other lawful acts." *See* NS Br. Ex. E at 3. Similar to the language in the first assignment agreement in *Aerocrine*, the obligations of Drs. Fletcher and McClorey specifically relate to executing written instruments and documents. *Compare Aerocrine*, 267 F.R.D. at 109-10 *with* NS Br. Ex. E at 3. Because the UWA Assignment Agreement requires only signing documents and does not "specifically contemplate the provision of testimony for purposes of enforcing patent rights," neither UWA nor Sarepta, can compel Drs. Fletcher or McClorey to appear for deposition. *Aerocrine*, 267 F.R.D. at 112. This should end the inquiry.

IV. EVEN IF UWA OR SAREPTA COULD COMPEL DRS. FLETCHER OR MCCLOREY TO TESTIFY, NS HAS FAILED TO SHOW IT NEEDS THEIR DEPOSITIONS

The scope of permissible discovery is limited to "any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering . . . the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit." Fed. R. Civ. P. 26(b)(1). "Generally, a party moving to compel discovery bears the burden of demonstrating the relevance of the requested information." *Delaware Display Group LLC v. Lenovo Group Ltd.*, C.A. No. 13–2108–RGA, 2016 WL 720977, at *2 (D. Del. Feb. 23, 2016) (citation omitted). NS's opening brief, and its actions throughout the meet and confer process regarding Sarepta's request for the deposition of Dr. Takeda, reveal that NS does not need the depositions of Drs. Fletcher or McClorey. NS's framing of its request makes this clear: "NS requests, as a matter of fairness and proportionality, that the Court compel equal numbers of inventor depositions." NS Br. at 5; *see also* Ex. N at 1 ("NS is making two of its inventors available in June for deposition while Sarepta is only willing to offer Dr. Wilton."). NS provides no authority for the assertion that a motion to compel should be granted based on making the number of inventors deposed equal rather than relevance and need for the case. As explained in Sarepta's opening letter, Dr. Takeda's assignment agreement with NS expressly requires him to offer testimony in this proceeding (*see* Sarepta Br. at 1-3 & Ex. A at 3); the UWA Assignment Agreement executed by Drs. Fletcher and McClorey does not. That NS is required to produce Dr. Takeda by virtue of the assignment agreement he executed, but UWA and Sarepta are not required to produce Drs. Fletcher and McClorey, is a consequence of the language of these respective agreements. Further, contrary to NS's suggestion in its motion, Drs. Fletcher and McClorey are not obligated by virtue of a retention agreement with Finnegan to provide testimony in this litigation.

The only attempts NS makes to carry its burden on relevance are to excerpt, out-of-context, a few lines from the then-ongoing deposition of the third UWA inventor, Dr. Wilton: vague references to document productions and an unexplained reference to NS's motion for leave to amend to assert inequitable conduct and *Walker Process* claims. NS Br. at 6-7. With respect to the deposition of Dr. Wilton (the lead inventor of the UWA patents who worked directly with Drs. Fletcher and McClorey) [redacted].[5] It is telling that NS makes so much of a few cherry-picked lines of testimony from a deposition it was ***still taking*** at 5 PM ET on June 15th when it filed its opening letter brief; the clear implication is that NS had little grounding for its arguments when it raised this "dispute" a week earlier.

[5] *See* note 2, *supra.* NS's citation to Dr. Wilton's "testimony" is even more egregious since it was apparently a dictation of the ongoing realtime feed; there was no transcript at the time.

Regarding Dr. Fletcher's exon 53 skipping work, Dr. Wilton explained [redacted]. And regarding Dr. McClorey, Dr. Wilton again noted [redacted] Regarding Dr. Fletcher, Dr. Wilton stated that [redacted] As for Dr. McClorey, Dr. Wilton explained [redacted]. Dr. Wilton answered the questions NS asked him regarding the respective contribution of Drs. Fletchers and McClorey, and they had the opportunity to ask as much follow-up as they wanted. NS demurred.

With respect to production of relevant documents, to date, Dr. Wilton, [redacted] Sarepta has additionally produced [redacted]. It is unclear what relevance this has, if any, to the depositions of Drs. Fletcher and McClorey. Finally, with respect to NS's motion for leave to amend to assert inequitable conduct and *Walker Process* claims, the lack of relevance or importance of testimony from Drs. Fletcher and McClorey is illustrated by NS's own (in)action in this case: NS has not taken any steps to secure discovery from these two foreign nationals living abroad. Even now, it only raised this request as a knee-jerk reaction to Sarepta's motion to compel a deposition of Dr. Takeda, a current NCNP employee with unique knowledge who signed an agreement obligating him to testify in the United States. This highlights the irrelevance and lack of proportionality of the testimony NS belatedly seeks.

For these reasons, not only is there no legal basis to compel these two foreign nationals, who are not employees of a party and who are not contractually obligated to do so, to sit for deposition, but there is also no reason to.[6]

Respectfully,

/s/ Megan E. Dellinger

Megan E. Dellinger (#5739)

MED:lo
Attachments
cc: All Counsel of Record (via electronic mail; w/attachments)

[6] To the extent the Special Master is inclined to grant NS's motion to compel Sarepta to try to produce *both* inventors, Sarepta would additionally request the Special Master to compel NS to try to produce Dr. Tetsuya Nagata for deposition, as well. Like Drs. Fletcher and McClorey, Dr. Nagata is a former employee. But unlike Drs. Fletcher and McClorey, he signed an assignment agreement obligating him to testify. Sarepta Br. Ex. A at 3.

CERTIFICATE OF SERVICE

I hereby certify that on June 19, 2023, copies of the foregoing were caused to be served upon the following in the manner indicated:

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APPENDIX
379-382

EXHIBIT M

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

REGENXBIO INC. and THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA,

Plaintiffs,

v.

SAREPTA THERAPEUTICS, INC. and SAREPTA THERAPEUTICS THREE, LLC,

Defendants.

C.A. No. 20-1226-RGA

J. Caleb Boggs Courthouse
844 North King Street
Wilmington, Delaware

Tuesday, May 2, 2023
3:00 p.m.
Discovery Dispute Conference

BEFORE: THE HONORABLE RICHARD G. ANDREWS, U.S.D.C.J.

APPEARANCES:

FISH & RICHARDSON
BY: SUSAN MORRISON, ESQUIRE

For the Plaintiff

MORRIS NICHOLS ARSHT & TUNNELL LLP
BY: DEREK FAHNESTOCK, ESQUIRE

-and-

QUINN EMANUEL URQUHART & SULLIVAN
BY: ANASTASIA M. FERNANDS, ESQUIRE

For the Defendant

02:51:58

02:51:58 *** PROCEEDINGS ***

03:01:03 DEPUTY CLERK: All rise. Court is now in session. The Honorable Richard G. Andrews presiding.

03:02:31 THE COURT: All right. Good afternoon. Please be seated.

03:02:35 We're here in the *Trustee of the University of Pennsylvania, et al vs Sarepta*.

03:02:45 Ms. Morrison, your client, how do you pronounce their name?

03:02:51 MS. MORRISON: It's Regenxbio.

03:02:53 THE COURT: Regenxbio?

03:02:54 MS. MORRISON: Regenxbio.

03:02:55 THE COURT: Oh, okay.

03:02:56 All right. All right.

03:02:59 So, and I see Ms. Morrison there.

03:03:01 And Mr. Fahnestock; right?

03:03:06 And presumably, you are -- I'm not sure about his handwriting. You are?

03:03:12 MS. FERNANDS: Ms. Fernands.

03:03:15 THE COURT: Ms. Fernands?

03:03:17 MS. FERNANDS: Yes.

03:03:17 THE COURT: So, okay. So, I read your letters, and I asked the Defendant to bring along two unredacted versions and two redacted versions.

03:03:32 And so, what I had in mind doing was asking

03:03:36 Ms. Morrison to sort of tell me where she thought some of the good information might be, and I would see if it was there.

03:03:48 So, as I understand it, the notes I made to myself here was that the Plaintiff's theory is that this agreement was relevant to the safe harbor and to damages. And as I sort of understood it, I think the response of the Defendant here was, We provided you with all the information about all of the SRP-9001 that we made.

03:04:30 Is that right, Ms. Morrison?

03:04:45 MS. MORRISON: I'm sorry, Your Honor. Is it --

03:04:47 THE COURT: No, that's all right. You can stand there for a second.

03:04:50 Basically, has the Defendant provided you, Here's all the times we made SRP-9001 in the United States and presumably what we have done with it?

03:04:52 MS. MORRISON: So, that is -- I believe it's not a hundred percent correct, Your Honor. We still are having a discussion about some batch records. I'm not the closest to that issue on my team, but I believe there's still discussion going on about whether there are some missing batch records and whether we actually have all that information, but that's -- so, I think that's still up for debate. But I think the parties are working on that piece of it in terms of whether we have everything.

03:05:34 MS. FERNANDS: What we have and we've represented to Plaintiffs many times is we have produced a spreadsheet of all batches of SRP-9001 drug product produced prior to the expiration of the patent in November of 2012.

03:05:50 As Ms. Morrison has indicated, there are some batch records related to -- they have the spreadsheet of all final product produced. There are some batch records that the manufacturer has not released yet, so my client doesn't have them yet. And we represented that we'll provide those backup batch records as we receive them, but they have the spreadsheet of everything that has been made as of the expiration of the patent.

03:06:12 THE COURT: And so, the stuff that was made as of the expiration of the patent, Ms. Fernands, what happened to that stuff?

03:06:27 MS. FERNANDS: [redacted] there has been no approval yet. The BLA has been submitted and not approved. There's no commercial approval. And so, there are ongoing clinical trials, but, [redacted]

03:06:48 THE COURT: And so, they're sitting there two years, or I forget what the date was that you said that the patent expired, but maybe not two years, but a decent chunk of time after the patent expired. It's just sitting there.

03:12:18 10K.
03:12:18 MS. MORRISON: It was attached to a 10K. So, he had it, and they also produced that version. And so, he was able to rely upon it.
03:12:25 And in that, he relied upon it because that Roche agreement was signed just about, I believe --
03:12:31 THE COURT: Right, right. I gather it was within a month or something.
03:12:34 MS. MORRISON: Yes, very close to the time of the hypothetical negotiation. And so, it's highly relevant to the Sarepta negotiator's state of mind coming to the hypothetical negotiation about how important having a license would be to Sarepta.
03:12:47 And so, I can't tell Your Honor what is in the global development plan because I haven't seen it, but that is one area where Regenxbio's facts, we can do nothing more than suspect based on what's in the agreement. It's an informed suspicion, I would say, that there are items in that global development plan that would be relevant to the damages analysis because it would inform Sarepta's position coming to the hypothetical negotiation. And our damages expert did rely pretty extensively on the redacted version of the Roche agreement in his expert report.
03:13:29 And so, we do think it's -- I can't tell you what exactly is in these sections that we don't have, of

03:13:36 course, but I can give you a suspicion of what might be there.
03:13:39 THE COURT: Well, so one of the things that was said in the letter and, of course, Sarepta went second, was there's a lot of other things in the global development or in the agreement, and there were two things in particular. One of them was something like exon and the other was something else.
03:14:04 And that, in so many words, there's just a whole lot of different things going on at once that have nothing to do with the patent and the cultured cells. What in his report or her report did your expert do about -- how did they address things like that?
03:14:37 MS. MORRISON: So, I think what you're referring to is the portions of the agreement that relate to exon skipping and gene editing.
03:14:46 THE COURT: Okay. Yes.
03:14:48 MS. MORRISON: So, frankly, those are -- and I think we've already said this to Sarepta, those are parts of the agreements that we don't -- we're not interested in, but -- and we would agree to not have those parts of the agreement because they're not particularly relevant. But the portions of the agreement our damages expert relied upon are specific to the agreement about the gene therapy that is made using the patented cultured host cells.

03:15:17 THE COURT: Okay.
03:15:18 MS. MORRISON: And so -- I'm sorry, Your Honor.
03:15:19 THE COURT: No, no, no. I thought you were pausing there.
03:15:23 So, why don't we do this. Why don't I get -- because you could probably point me to in the agreement where you think this stuff is that you'd like to have; right?
03:15:37 MS. MORRISON: I certainly can try, Your Honor.
03:15:38 THE COURT: All right. Well, before you try, can we get two redacted and two unredacted, one for me and one for my excellent assistant here?
03:15:49 MS. FERNANDS: Okay. So, when Your Honor asked for a highlighted, we actually highlighted the unredacted with everything that is redacted.
03:15:53 THE COURT: Okay. So, in other words -- okay.
03:15:58 MS. FERNANDS: I think that might be --
03:16:02 THE COURT: Yeah, yeah. You know --
03:16:04 MS. FERNANDS: I can also bring an unredacted or a clean one.
03:16:05 THE COURT: No, no. If it's yellow --
03:16:08 MS. FERNANDS: It is -- I brought three different varieties, but I think that might be the most efficient way to see what was redacted.
03:16:10 THE COURT: And so, the yellow is the stuff that

03:16:14 was redacted?
03:16:17 MS. FERNANDS: Was redacted from the public version, correct.
03:16:19 THE COURT: So, Ms. Morrison, where would you like to direct me to and you better, I guess -- because the pagination you have is probably different than the pagination of the one I just got.
03:16:23 MS. MORRISON: It is. And what I have, Your Honor, are section numbers --
03:16:24 THE COURT: Right. So, go ahead.
03:16:25 MS. MORRISON: -- which are, in some senses, partially. So, I'll start with the one -- there's quite a few, Your Honor, so I'm not sure how many of these you would like me to --
03:16:27 THE COURT: Well, there's a magic to the number three.
03:16:32 MS. MORRISON: Okay.
03:16:35 THE COURT: So, why don't you give me your best three.
03:16:36 MS. MORRISON: All right. Let me look at the sections that were highlighted for me here.
03:16:37 So, one that's missing -- we believe is partially redacted that's missing information would be Section 8.4.1.
03:16:39 THE COURT: Okay.

04:06:16 you know, are not direct evidence of value of the cultured
04:06:23 cells or the production method, you know, there's both
04:06:31 quantitative and qualitative.
04:06:33 And it may be that some of this is similar or
04:06:37 different, I don't know, to the actual -- to the projections
04:06:46 that were made. Maybe the projections should be roughly the
04:06:50 same because -- well, you would think they would be somewhat
04:06:56 close.
04:06:56 But I think that for an expert to be relying on
04:07:04 a license, even for state of mind, it's a big handicap not
04:07:11 to have the entire agreement available to him so that he can
04:07:21 decide what there is in it that is relevant to his
04:07:28 undertaking.
04:07:29 And, you know, I think the lead -- it seems to
04:07:35 me at least reasonable to say that the lead product
04:07:38 information is relevant to his undertaking, which is partly
04:07:44 based on the fact that in the expert report, he's managed to
04:07:51 use the agreement as part of his support for his opinions.
04:08:02 And so, having a high degree of confidence in
04:08:09 the Confidentiality Order, and I think it should be
04:08:23 produced.
04:08:25 MS. FERNANDS: May we produce in a redacted form
04:08:27 with the exon skipping and gene editing all removed?
04:08:31 MS. MORRISON: Your Honor, we don't have any
04:08:32 objection to that other than our concern that as long as

04:08:36 that is all that's removed, I don't have a concern about
04:08:39 that. And as long as --
04:08:41 THE COURT: Okay.
04:08:41 MS. MORRISON: As long as our expert isn't going
04:08:43 to be cross-examined with, You didn't have the complete
04:08:47 agreement, that's my only concern, to be honest. We're not
04:08:52 going to use those parts, but --
04:08:54 THE COURT: All right. Well, it seems to me,
04:08:56 then, that you should redact those parts, that is,
04:09:00 essentially the pricing parts. The rest of it --
04:09:09 MS. FERNANDS: With respect to the schedules,
04:09:11 may I also ask with the schedules that we focused on that
04:09:16 were, as you saw, only three pages that are arguably
04:09:19 financial in the schedule that they pointed to, and the rest
04:09:22 goes to what I'd say technical or clinical.
04:09:29 THE COURT: No, I think the technical and
04:09:38 clinical, I would think isn't going to make too much
04:09:41 difference to a damages expert because I'm assuming he's
04:09:46 probably not a whole lot better qualified than me to make
04:09:49 sense of it. But I think, you know, basically the redaction
04:10:05 of the exon skipping and the gene splicing, everyone agrees
04:10:15 those dollars are just irrelevant. And we're not going to
04:10:19 have arguments later on about whether or not you redacted
04:10:22 too much, and I'd prefer to avoid that.
04:10:25 I prefer to avoid having -- that it's real clear

04:10:29 what has been redacted. And so, basically the dollar
04:10:36 figures for these things that are not the lead product or
04:10:44 the gene therapy product, yeah, you can do that, but
04:10:49 otherwise, you ought to give over a clean agreement.
04:10:54 Okay?
04:10:54 MS. FERNANDS: May I ask, and I hope this won't
04:10:56 be controversial, schedule 11.6.2 is a Roche internal
04:11:01 document concerning Roche compliance policies. It's a
04:11:05 rather long document. It is -- I think there's -- I think
04:11:10 it's listed in the -- 11.6.2 is listed in the public version
04:11:15 of schedules, I think. But, Your Honor, you can see in the
04:11:18 version that you have that it is a document with a Roche
04:11:22 header.
04:11:22 THE COURT: It's 100 percent redacted; right?
04:11:25 MS. FERNANDS: It was 100 percent redacted.
04:11:27 Only the title was in the public.
04:11:28 THE COURT: It seems --
04:11:34 MS. MORRISON: Without having seen it, it's
04:11:35 difficult for me to say, but I will accept Ms. Fernands'
04:11:40 representation.
04:11:40 THE COURT: Well, I mean, just looking at it, I
04:11:42 mean, it really is like a statement of corporate policy that
04:11:45 has nothing to do with -- I think this has nothing to do
04:11:51 with this contract in particular; right?
04:11:53 MS. FERNANDS: That is my understanding, and it

04:11:55 certainly is not even my client's information. It's our
04:11:58 co-development partner's information.
04:12:00 THE COURT: All right. Well, I understand --
04:12:02 so, you can redact that. Okay?
04:12:08 All right. And I assume you'll be able to
04:12:11 produce -- to do those two, the one little set of redactions
04:12:15 for dollar figures and the Roche corporate policy and
04:12:20 produce this, you know, like by the end of the week?
04:12:23 MS. FERNANDS: Yes, we should be able to produce
04:12:26 it by the end of the week, Your Honor.
04:12:27 THE COURT: Okay. Well, thank you. It's an
04:12:29 interesting problem you all have.
04:12:30 We'll be in recess.
04:12:32 DEPUTY CLERK: All rise.
04:12:32 THE COURT: The transcript will serve as my
04:12:35 Order.

(Court was recessed at 4:12 p.m.)

I hereby certify the foregoing is a true and accurate transcript from my stenographic notes in the proceeding.

/s/ Heather M. Triozzi
Certified Merit and Real-Time Reporter
U.S. District Court

CERTIFICATE OF SERVICE

I hereby certify that on August 7, 2023, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on August 7, 2023, upon the following in the manner indicated:

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